PB81-145732

Chemical Screening: Initial Evaluations of Substantial Risk Notices, Section 8(e) July 1, 1979 to January 31, 1980. Volume 2

(U.S.) Environmental Protection Agency
Washington, DC

Jul 80

U.S. Department of Commerce
National Technical Information Service
NTIS

United States
Environmental Protection
Agency

Office of Pesticides
and Toxic Substances
Washington, D.C. 20460

EPA 560/11-80-020
July 1980

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Toxic Substances

EPA

TSCA Chemical Asessment Series

Chemical Screening: Initial Evaluations of Substantial Risk Notices, Section 8(e)

July 1, 1979 - January 31, 1980

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U.S. DEPARTMENT OF COMMERCE
SPRINGFIELD, VA 22161

NOTICE TO ADMINISTRATOR OF SUBSTANTIAL RISKS. Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

--Section 8(e), Toxic Substance Control Act (1976)

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16. ABSTRACT

This collection of Status Reports (initial evaluations) was prepared by scientists in the EPA Office of Pesticides and Toxic Substances (OPTS) on submissions received between July 1, 1979 and January 31, 1980 from chemical manufacturers, processors, and distributors under Section 8(e) of the Toxic Substances Control Act (TSCA). The volume is being published for two reasons. First, the collection of status reports in a single volume will make that information more accessible to the public. Second, the volume may, by providing specific examples of submitted information and EPA's evaluation of it, help anyone subject to Section 8(e) to understand better the types of information that should be submitted to the Agency.

To date, no information submitted under Section 8(e) has resulted in immediate regulatory action under TSCA or any other act, although some submitted information has triggered further data gathering and evaluation that may lead to proposal of regulations in the future.

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CHEMICAL SCREENING: INITIAL EVALUATIONS OF SUBSTANTIAL RISK NOTICES, SECTION 8(e) JULY 1, 1979, TO JANUARY 31, 1980

Volume 2

Office of Testing and Evaluation
Office of Pesticides and Toxic Substances
Washington, DC 20460

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES AND TOXIC SUBSTANCES
WASHINGTON, DC 20460

Disclaimer

This volume has been reviewed by the Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, and approved for publication. The status reports published in this volume present the Agency's preliminary evaluations of the submitted information; they do not represent final Agency policy or intent with respect to the submissions or the subject chemicals. Mention of company names, trade names, or commercial products does not constitute Agency endorsement or recommendation.

Foreword

Evaluations of chemical substances prepared by scientists in EPA's Office of Testing and Evaluation, Office of Pesticides and Toxic Substances (OPTS), to implement provisions in the Toxic Substances Control Act (TSCA), will be published periodically and made available to the public in the TSCA Chemical Assessment Series. Some of the volumes in the Series will be reports on single chemicals; others will be compendiums of information received and evaluated by the Agency about many chemicals. (The anticipated frequency of publication will vary among titles: some will be published annually, some semiannually, and others quarterly.)

Because the chemical assessments published in this Series often will reflect initial or intermediate steps in EPA's evaluation of a chemical under TSCA, the Agency welcomes the submission of additional information for or comments on its evaluations. Such submissions will be considered either at a subsequent step in the assessment of the subject chemical or in the decision not to proceed with further evaluation.

All information for or comments on volumes in the TSCA Chemical Assessment Series should be submitted to:

Document Control Officer (TS-793)
Office of Pesticides and Toxic Substances
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Comments on this volume should bear the identifying docket number OPTS-10004.

The TSCA Chemical Assessment Series is being distributed through the Industry Assistance Office (IAO) in OPTS. IAO is maintaining two mailing lists: a subscription list of persons who want to receive all volumes in the Series and a notification list of persons who want to receive announcements of individual volumes as they become available. For a place on either IAO list, telephone IAO (toll-free 800-424-9065 or, in Washington, D.C., 554-1404) or write to:

Industry Assistance Office (TS-799)
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460
Toll Free: (800-424-9065)
Washington, D.C.: (554-1404)

Generally, five thousand copies of each volume will be printed. After this supply is exhausted, copies can be purchased from the National Technical Information Service (NTIS), whose "PB" reference number can be found in the OPTS "Comprehensive List of Scientific and Technical Reports," also available from IAO.

The status reports (evaluations) prepared by OPTS on submissions received from chemical manufacturers, processors, and distributors between July 1, 1979, and January 31, 1980, under Section 8(e) of TSCA (90 Stat. 2029, 15 U.S.C. 2607), are presented in chronologic order in this volume. Status reports are prepared by OPTS on all formal submissions received under Section 8(e) and on other similar types of information received by EPA. All Section 8(e) submissions and the resulting status reports are placed in a public file (subject to claims of confidentiality made by the submitter) upon their receipt or completion.

EPA is publishing this volume for two reasons. First, the collection of status reports in a single volume will make that information more accessible to the public. Second, the volume may, by providing specific examples of submitted information and EPA's evaluation of it, help anyone subject to Section 8(e) to understand better the types of information that should be submitted to the EPA.

To date, no information submitted under Section 8(e) has resulted in immediate regulatory action under TSCA or any other act, although some submitted information has triggered further data gathering and evaluation that may lead to proposal of regulations in the future.

The original submissions, as well as all status reports, can be viewed at EPA Headquarters (Room 447 East Tower), 401 "M" Street, S.W., Washington, D.C.

Joseph J. Merenda
Director, Assessment Division

Contents

Foreword iii

Acknowledgment vii

Introduction 1

Status Reports 8EHQ-0779-0292 to 8EHQ-0180-0330 9

Supplemental and Follow-up Status Reports 90

Appendix A. Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk (43 FR 11110, March 16, 1978) 102

Appendix B. List of Status Reports Alphabetized by Chemical Name 110

Appendix C. List of Status Reports Arranged by CAS Registry Number 115

Appendix D. List of Status Reports Arranged by Study Type 118

Appendix E. List of Status Reports Arranged by Submission Number 120

Acknowledgment

In preparing the status reports contained in this volume, staff of the Office of Pesticides and Toxic Substances (OPTS) have frequently found it necessary to request further information about or clarification of the submitted data. OPTS appreciates the effort and cooperation of those companies and organizations that have submitted the information evaluated in this volume:

Aerojet-General Corporation
American Cyanamid Company
American Petroleum Institute
Atlantic Richfield Company
Celanese Corporation
Chemical Industry Institute of Toxicology
Ciba-Geigy Corporation
Cincinnati Milacron Chemicals, Inc.
Clorox Company
Diamond Shamrock Corporation
E.I. du Pont de Nemours & Company
Ethyl Corporation
Exxon Company, USA
Exxon Corporation
FMC Corporation
General Electric Company
Gulf Mineral Resources Company
IBM Corporation
International Salt Company
PPG Industries, Inc.
Procter and Gamble Company
Shell Oil Company
Sherex Chemical Company, Inc.
Standard Oil Company (Indiana)
Texaco, Inc.
Toms River Chemical Corporation
Union Carbide Corporation
Union Oil Company of California

Introduction

Section 8(e) of TSCA states that "any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information." Section 8(e) was self-effectuating and required no implementing rules; therefore, manufacturers, processors, and distributors of chemicals became subject to Section 8(e) as of January 1, 1977, the effective date of TSCA. To provide further guidance to those subject to Section 8(e), on March 16, 1978, after having received comment on a proposed statement of policy published earlier in the Federal Register, EPA published a "Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" (43 FR 11110). For easy referral when using this volume, the March 16, 1978, statement has been reproduced as Appendix A.

The March 16, 1978, statement expresses the Agency policy that information subject to Section 8(e) is any information that provides "reasonable support" for the conclusion that a chemical presents a substantial risk of injury but need not necessarily conclusively indicate such risk. A determination of "substantial risk" does not include evaluation of economic or social benefits of the use of the chemical and, therefore, is not synonymous with the term "unreasonable risk" used in other sections of TSCA. Receipt of information under Section 8(e) of TSCA does not necessarily trigger immediate regulatory action; however, information submitted under Section 8(e) is given priority for evaluation in order to determine an Agency course of action. An action may, for example, be further evaluation by EPA or referral to another agency. To date, no information submitted under Section 8(e) has resulted in immediate regulatory action under TSCA, although some submitted information has triggered further data gathering and evaluation that may lead to proposal of regulations in the future.

Of the initial submissions received and evaluated by EPA as Section 8(e) information between January 1, 1977, and June 30, 1979, (Volume 1) approximately 100 were received before the publication of the March 16, 1978, statement; thus, the submitters did not have the benefit of that guidance. * Approximately 25 percent of the initial submissions received were sent to the Agency with the caveat that the submitter was

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* See U.S. Environmental Protection Agency. 1980. Chemical screening: initial evaluations of substantial risk notices, section 8(e), vol. 1. Washington, DC: Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency. EPA 560/11-80-008.

uncertain of the applicability of the information to Section 8(e). Some submitters stated that their reports were sent for information purposes or under other provisions of TSCA, although EPA believes that some of those reports are appropriate for submission under Section 8(e). A number of submissions appear to have been sent out of an abundance of caution, and, considering their content, did not in EPA's judgment warrant submission under Section 8(e). Regardless of the nature of the submissions, EPA has evaluated and prepared a status report for each one.

Figure 1 depicts the Agency's handling procedures for information received under Section 8(e). Information is first received by the OPTS Document Control Officer, who is located in the Chemical Information Division of EPA's Office of Pesticides and Toxic Substances. The Document Control Officer checks the notice for any information claimed by the submitter to be confidential and assigns a Document Control Number. The Document Control Number is used by the Agency to identify specific submissions and takes the following form: 8EHQ-0000-0000. Starting from the left, the first four symbols identify the information as a Section 8(e) submission received by EPA headquarters; the next four digits identify the month and year (e.g., -0579-) of receipt of the information; the final four digits identify the submission's chronological number. In addition to the basic sequence, characters may be added to the right end of the Document Control Number to convey a special status. The characters and their meaning follow:

C: contains confidential business information; access is limited to persons with appropriate clearance;
S: denotes the "sanitized" version of a confidential document; and
P: signals that the original document contains the names or other identification of individuals, the release of which may violate the Privacy Act (such documents are sanitized to remove the names or other identifiers).

The Document Control Officer next enters the information into the appropriate file: the nonconfidential and sanitized submissions enter the public file, while copies containing confidential business information are placed in the confidential file. A letter acknowledging receipt of the Section 8(e) submission is prepared by the Document Control Officer and sent to the submitter. In the case of submissions containing confidential data, the Document Control Officer sends a letter asking the submitter to support any confidentiality claims by providing the information requested in an attachment to the letter entitled "Support Information for Confidentiality Claims." This attachment is reproduced as Figure 2. The submitter has 15 working days from the date of receipt of this letter to provide EPA with the requested information. When the Document Control Officer receives the requested support information from the submitter, it is forwarded to the EPA Office of General Counsel for review, in accordance with Agency procedures. No information claimed by the submitter as confidential will be included in any file to which the public has access before the Agency's regulations affecting confidential business information have been complied with fully. This means that, before any claim for confidentiality is denied, fair and adequate notice will be given to any person who has made a claim of confidentiality. If a claimant disagrees with EPA'S determination on the confidentiality of a piece of information, that person will have adequate opportunity to challenge release of the information to the public.

Following receipt of the submission by the Chemical Information Division, the submitted information is evaluated in OPTS to determine its significance and to decide what action, if any, is indicated. Submissions containing confidential data can be handled only by persons with appropriate clearance. Most Section 8(e) submissions are evaluated by staff in the Chemical Hazard Identification Branch of the Assessment Division in OPTS, in consultation with appropriate scientists from that Division and/or other units of the Office of Testing and Evaluation. The procedures used in making such evaluations are described below. In the case of submissions reporting "emergency incidents of environmental contamination" (see Part V [c] of the March 16, 1978, policy statement), however, the initial evaluation is performed by staff in the Program Integration Division in OPTS, with scientific support as necessary from the Office of Testing and Evaluation.

Upon receipt of a Section 8(e) submission from the OPTS Document Control Officer, the Section 8(e) coordinator in the Chemical Hazard Identification Branch scans the information to determine the type of submission (e.g., mammalian laboratory study, fish bioaccumulation study, epidemiologic study, etc.) and its apparent significance. The coordinator next forwards a copy of the submission to an appropriate scientist in the Office of Testing and Evaluation, who performs an initial evaluation of the submission and prepares written comments on it. When the comments are returned to the coordinator, a status report evaluating the submission is prepared. The basic format of a status report is shown in Figure 3. The Chief of the Chemical Hazard Identification Branch reviews the prepared status report and resolves any questions with the Section 8(e) coordinator before signing the report. Next, the Director of the Assessment Division reviews the status report and either approves the report or asks for clarification. Following approval of the status report by the Division Director, follow-up activities on the submission are initiated. These include delivery of a copy of the status report to the Chemical Information Division for inclusion in the public file, transmittal to other EPA offices or Federal agencies, and preparation of a follow-up letter to the submitter. This letter transmits a copy of the status report and may ask for clarification of or additional information on the submission. Clarification is necessary when submissions are incomplete or when the content of the submission does not appear to "reasonably support" a conclusion of substantial risk.

Review of notices concerning emergency incidents of environmental contamination is handled in similar fashion by the Program Integration Division, with technical support as necessary from the Office of Testing and Evaluation. The Program Integration Division has lead responsibility for review of these items to ensure full and rapid coordination with appropriate EPA regional office personnel. The Program Integration Division has the responsibility in OPTS for coordination of headquarters and regional efforts related to toxic substances.

When reviewing a status report, the reader should remember that the purpose of EPA's evaluation is to determine the significance of the submitted information in terms of a need for possible action by the Agency. This determination involves a critical analysis of the notice to evaluate the extent to which the reported hazard is supported by the submitted information. However, the scope of the initial evaluation generally is limited to the submitted documents and to any closely related information known by the reviewer. Neither a literature search to identify other reported effects nor an in-depth analysis of possible sources of exposure to the subject chemical is part of the submission evaluation. Therefore, a status report should be viewed only as an initial review of the submitted information, not as a comprehensive assessment of the chemical for which a Section 8(e) submission has been made.

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Figure 1

PROCESSING OF 8(e) NOTICES OF SUBSTANTIAL RISK

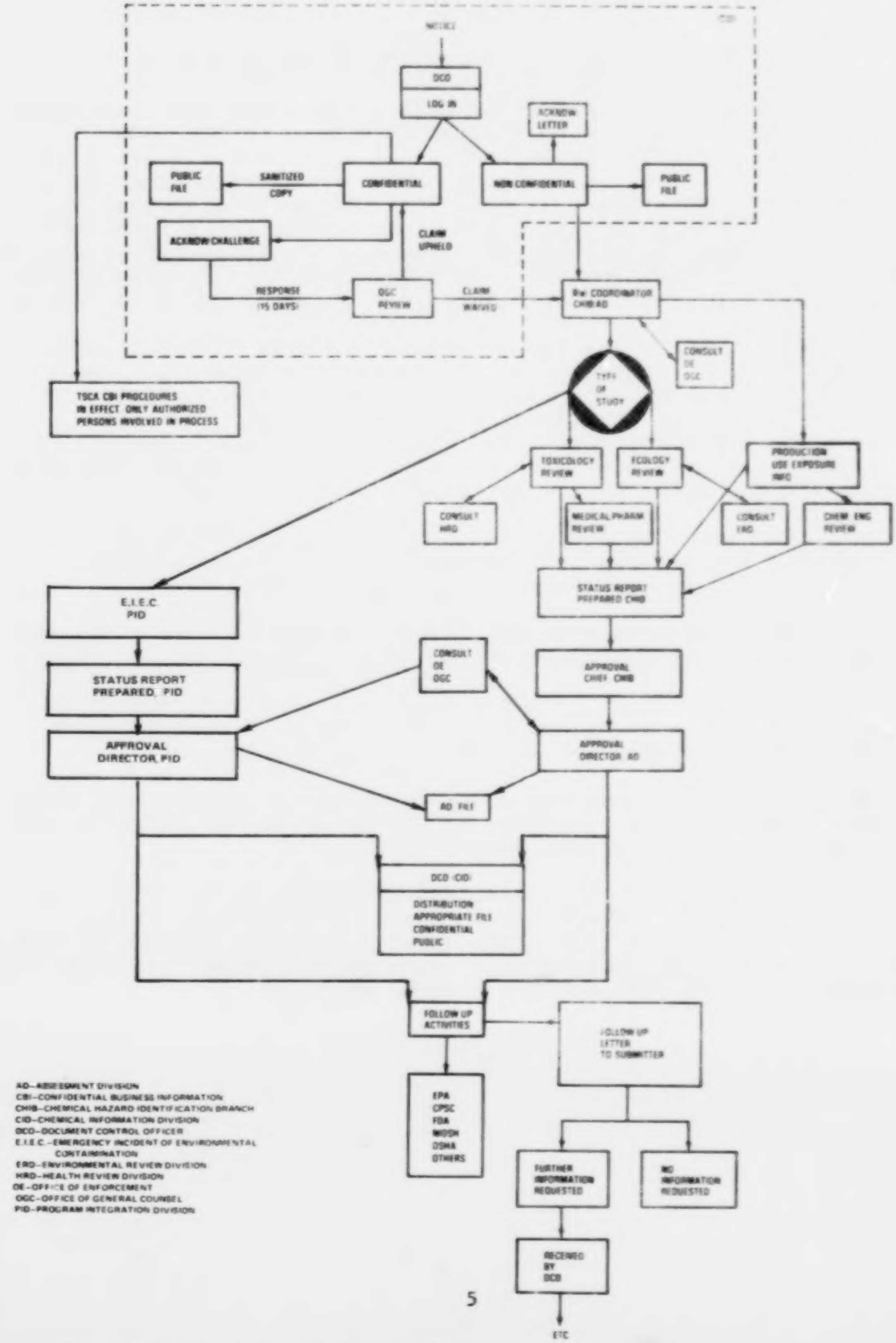
(CBI)
NOTICE
DCO
LOG IN
ACKNOW LETTER
PUBLIC FILE
SANITIZED COPY
CONFIDENTIAL
NON CONFIDENTIAL
PUBLIC FILE
ACKNOW/CHALLENGE
CLAIM UPHELD
RESPONSE (15 DAYS)
OGC REVIEW
CLAIM WAIVED
8(e) COORDINATOR CHIB AD
CONSULT OE OGC
TSCA CBI PROCEDURES IN EFFECT ONLY AUTHORIZED PERSONS INVOLVED IN PROCESS
TYPE OF STUDY
TOXICOLOGY REVIEW
ECOLOGY REVIEW
PRODUCTION USE EXPOSURE INFO
CONSULT HRD
MEDICAL PHARM REVIEW
CONSULT ERD
CHEM ENG REVIEW
E.I.E.C. PID
STATUS REPORT PREPARED CHIB
STATUS REPORT PREPARED, PID
CONSULT OE OGC
APPROVAL CHIEF CHIB
APPROVAL DIRECTOR, PID
APPROVAL DIRECTOR AD
AD FILE
DCO (CID)
DISTRIBUTION APPROPRIATE FILE CONFIDENTIAL PUBLIC
FOLLOW UP ACTIVITIES
FOLLOW UP LETTER TO SUBMITTER
EPA
CPSC
FDA
NIOSH
OSHA
OTHERS
FURTHER INFORMATION REQUESTED
NO INFORMATION REQUESTED
RECEIVED BY DCO
ETC
AD–ASSESSMENT DIVISION
CBI–CONFIDENTIAL BUSINESS INFORMATION
CHIB–CHEMICAL HAZARD IDENTIFICATION BRANCH
CID–CHEMICAL INFORMATION DIVISION
DCO–DOCUMENT CONTROL OFFICER
E.I.E.C.–EMERGENCY INCIDENT OF ENVIRONMENTAL CONTAMINATION
ERD–ENVIRONMENTAL REVIEW DIVISION
HRD–HEALTH REVIEW DIVISION
OE–OFFICE OF ENFORCEMENT
OGC–OFFICE OF GENERAL COUNSEL
PID–PROGRAM INTEGRATION DIVISION

Figure 2

SUPPORT INFORMATION FOR CONFIDENTIALITY CLAIMS

The Environmental Protection Agency (EPA) has been receiving many requests for access to notices submitted to EPA under Section 8(e) of TSCA. Accordingly, EPA must make a final confidentiality determination concerning the treatment of the information in your submission. In order to make that determination, EPA needs further information from you. Under EPA's regulations on the treatment of information claimed as confidential in 40 CFR Part 2 (41 FR 36902, September 1, 1976), you have an opportunity to submit comments to substantiate your claim of confidentiality.

To comply with these requirements, you must indicate which portions of your submission are claimed as confidential. Be specific as to page, paragraph, or sentence as appropriate. For those portions that you identify as confidential, you must address the following questions. In answering the questions, be as specific as possible, give examples if necessary, and connect the specific answers to the specific claimed portions.

1. For how long a period do you desire confidential treatment? May EPA disclose this information after a certain date or after the occurrence of a specific event?

2. What measures have you taken to guard against undesired disclosure of this information to others?

3. To what extent have you disclosed this information to others, and what precautions have you taken in connection with the disclosures to protect against further disclosure?

4. Have there been any confidentiality determinations made by EPA, other federal agencies, or courts in connection with this information? If so, please enclose copies.

5. Do you assert that disclosure of this information would be likely to result in substantial harm to your competitive position? If so, what are those harmful effects, and why should they be regarded as substantial? What is the causal relationship between the disclosure and the harmful effects?

Figure 2 (cont.)

6. Do you assert that this information was voluntarily submitted as defined in 40 CFR 2.201(i)? If so, would the disclosure of this information tend to lessen the availability to the Government of similar information in the future? Why?

In making your claims of confidentiality and providing responses to the above questions, you should keep in mind that, under Section 14(b) of TSCA, "data from health and safety studies" are not entitled to confidential treatment, except to the extent that disclosure of such data would reveal either the portion of a mixture comprised of any of the chemical substances in the mixture or the processes used in manufacturing or processing a chemical substance or mixture. Any claim of confidentiality for data from health and safety studies that goes beyond these two types will be denied.

Figure 3

STATUS REPORT FORMAT

Submission Description

The content of the submission and the chemical(s) under discussion are identified in this section.

Submission Evaluation

Depending on the nature of the submission, either an environmental or health scientist will perform the initial evaluation. Comments generally include remarks on the experimental method, the significance of the results, points of agreement or disagreement with the conclusions offered, and any recommended actions. This section can vary in length from a brief paragraph to several paragraphs.

Current Production and Use

In this section the expected exposure to the chemical(s) is described, as estimated by production volume and use characteristics. The production volume information once taken from secondary literature is now derived from the nonconfidential TSCA Section 8(b) Chemical Inventory.

Comments/Recommendations

Additional comments that do not fit into the other sections of the status report are presented here. Such remarks include a listing of other submissions on the same chemical(s) and comments on the submission in general.

Recommendations include suggested referrals to other offices or agencies, the need for follow-up correspondence to the submitter to clarify a point, and possible EPA actions.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

8EHQ-0779-0292
Page 1 of 3

DATE: MAY 30 80

SUBJECT: Status Report 8EHQ-0779-0292

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division

Approved 6/2/80

Revision Needed

Submission Description

An employee of Bell Laboratories reports that an uncured bisphenol A-epichlorohydrin resin (EPON 828) is being used in Type 457 PVC telephone cord insulation which is then handled by large numbers of Bell System and Western Electric personnel. The submitter also reports that Western Electric industrial hygienists have measured small amounts of epichlorohydrin in the air surrounding the area where Type 457 PVC insulation is mixed. The submitter also states that recent evidence indicates that Type 457 PVC cord may have caused an allergic skin reaction in a customer.

In providing this information under TSCA Section 8(e) the submitter cites several literature references including the NIOSH documents which address the potential health hazards involved with exposure to epichlorohydrin and glycidyl ethers. (EPON 828 is the diglycidyl ether of bisphenol A).

Submission Evaluation

The health concerns expressed by the submitter are legitimate. The many toxicities of epichlorohydrin and glycidyl ethers have been well documented by NIOSH in its Criteria Documents and Current Intelligence Bulletins on these specific chemicals.

Current Production and Use

Epichlorohydrin is used as a major raw material for epoxy and phenoxy resins and is used in the manufacturing of glycerol. It also has uses in curing propylene-based rubbers, as a solvent for cellulose esters and ethers, and is used in preparing high wet-strength resins for the paper industry.

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

A review of the production range (including importation volumes) statistics for epichlorohydrin (CAS No. 106-89-8) which is listed in the initial TSCA Inventory has shown that between 251 million and 1.1 billion pounds of this chemical were reported as produced/ imported in 1977.**/

Bisphenol A-epichlorohydrin based resins are used in molding powders (e.g. encapsulation of electrical parts), protective coatings, reinforced plastics, bondings and adhesives, flooring, paving and other miscellaneous applications.

A review of the production range (includes importation volumes) statistics for bisphenol A-epichlorohydrin resins (CAS No. 25068-38-6) which are listed in the initial TSCA Inventory has shown that between 126 million and 669 million pounds were reported as produced/imported in 1977.**/

The Type 457 PVC telephone cord cited in this submission is the electrically insulated coiled cord which provides the connection between either a standard desk and/or wall telephone and the standard mouthpiece/earpiece handle. The PVC resin insulation contains Epon 828 uncured epoxy resin which acts as a non-spewing stabilizer which does not become tacky on use and performs the function of scavenging degradation products from polyvinyl chloride resin should the resin insulation start depolymerizing during its use life.

Comments/Recommendations

NIOSH has published criteria for recommended standards for the occupational exposure to glycidyl ethers (June, 1978) and epichlorohydrin (September, 1976). In addition, NIOSH has published Current Intelligence Bulletins on glycidyl ethers (No. 29, October 1978) and epichlorohydrin (No. 30, October, 1978).

The Test Rules Development Branch (TRDB/AD), in conjunction with the Environmental and Health Review Divisions/OTE, is currently reviewing data received by the EPA pertaining to the Interagency Testing Committee designated classes "Glycidol and Its Derivatives" and "Halogenated Alkyl Epoxides."

The Agency has received and evaluated several section 8(e) submissions on bisphenol A-epichlorohydrin resins (8EHQ-0579-0289 and 8EHQ-0579-0289 Supplement) and epichlorohydrin (8EHQ-1177-

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**/ This production range information does not include any production/importantion data claimed as confidential by the person(s) reporting for the TSCA Inventory, nor does it include any information which would compromise Confidential Business Information. The data submitted for the TSCA Inventory, including production range information, are subject to the limitations contained in the Inventory Reporting Regulations (40 CFR 710).

0016, 8EHQ-0878-0230, and 8EHQ-0978-0230 Supplement). The Agency has also received and evaluated submissions on a number of glycidyl ethers including n-BGE (n-butyl glycidyl ether; 8EHQ-0778-0213), t-BGE (t-butyl glycidyl ether; 8EHQ-0579-0285), PGE (phenyl glycidyl ether; 8EHQ-0279-0274), and n-alkyl glycidyl ethers with alkyl groups in the C_2-C_{10} range (8EHQ-0779-0293).

a) The Agency should transmit a copy of this submission and status report to Bell Laboratories. The company should be requested to provide its rationale as to why the information provided and concerns expressed by the submitting employee was not formally submitted by the company pursuant to TSCA Section 8(e). In addition, Bell Laboratories should be requested to describe the actions it has taken in response to the submitted information to warn workers, customers, and other companies to reduce or eliminate exposure to the subject chemicals/materials. The results from monitoring activities and laboratory studies (e.g. patch tests) on the subject chemicals/materials should also be requested from the company.

b) The EPA has contacted the NIOSH Health Hazard Evaluation Program in Cincinnati, Ohio, to determine what assistance their program could provide in cases such as this. A representative of the program forwarded copies of a NIOSH booklet which specifies that before NIOSH can act, a request for a health hazard evaluation must be made by one of the following: an employer representative; an authorized representative of the employees for collective bargaining purposes; an authorized representative of two or more employees; or one of three or less employees in the workplace. The booklet which contains a form which can be used to request a workplace evaluation should be sent to the submitting employee.

c) The Agency should transmit copies of this submission and status report to NIOSH, OSHA, CPSC, and TRDB/AD. In addition, the Industry Assistance Office (IAO/OPII) should consider transmitting copies of this submission and status report to the manufacturers of these types of resins.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 1 1979

8EHQ-0779-0293
Page 1 of 3

DATE: Revised (May 28, 1980)

SUBJECT: Status Report* 8EHQ-0779-0293

Approved ____

Revision
Needed ____

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division

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Submission Description

The Procter and Gamble Company has submitted the summarized results from a battery of mutagenicity tests of several n-alkyl glycidyl ethers. The submitter states that this preliminary information leads to a conclusion that C_2 through C_{10} n-alkyl glycidyl ethers are potential mutagens. The submission also cites results from safety studies performed at an earlier date which indicate that a mixture (composed predominantly of C_8 and C_{10} n-alkyl glycidyl ethers) can cause testicular lesions in certain animal species at high dose levels by atypical routes of administration. The submitter states, however, that these testicular effects were not corroborated in other studies.

Submission Evaluation

The evidence that glycidyl ethers have effects on testicular function continues to accumulate. The oral study in monkeys of the mixture of C_8 and C_{10} glycidyl ethers seems inappropriate for what the study was intended to demonstrate. Final copies of the cited studies on testicular function should be requested for further evaluation.

The submitter's conclusion regarding the potential mutagenicity of the n-alkyl (C_2-C_{10}) glycidyl ethers appears valid. However, without complete copies of the protocols, identification of the chemicals tested, and the actual data from the battery of mutagenicity tests, a full evaluation of the results as presented in this submission is not possible at this time.

It is not suprising that the mutagenic potency of the C_{12} alkyl glycidyl ether is lower than that for the shorter chain homologs.

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

Current Production and Use

A review of the production range (includes importation volumes) statistics for n-alkyl (C_8,C_{10}) glycidyl ether (CAS No. 68609-96-1) as listed in the initial TSCA Inventory (1977) has shown that between 1,000 and 10,000 pounds of this chemical were produced/-imported in 1977. This production range information does not include any production/importation data claimed as confidential by the person(s) reporting for the TSCA inventory, nor does it include any information which would compromise Confidential Business Information. The data submitted for the TSCA Inventory, including production range information, are subject to the limitations contained in the Inventory Reporting Regulations (40 CFR 710).

The submitter states that it has manufactured and sold a chemical mixture (which is composed predominantly of C_8 and C_{10} glycidyl ethers) which is used primarily as a reactive diluent in epoxy resin systems where it may constitute 10-15% of the final resin.

Comments/Recommendations

Glycidyl ethers have been the subject of several submissions received in the recent past under section 8(e). Phenyl glycidyl ether (PGE) was found to induce nasal tumors, an uncommon lesion, at 12 ppm in a two-year rat inhalation study (8EHQ-0279-0274); tertiary-butyl glycidyl ether (t-BGE) was found genetically active in several short-term mutagenicity assays (8EHQ-0579-0285); and n-butyl glycidyl ether (n-BGE) was found to have genetic activity in several short-term assays and possible effects on testicular function in rats (8EHQ-0279-0213). The similarity between the data offered in the present submission and in 8EHQ-0279-0213 is of interest. In both cases, the initially available data consisted of evidence of testicular effects in test animals following exposure to glycidyl ethers. The overall significance of these initial studies was, however, somewhat uncertain. However, upon receipt of data evidencing genetic activity in short-term mutagenicity assays, the EPA in its evaluation of 8EHQ-0279-0213, and the present submitter in their evaluation of the data contained in submission 8EHQ-0779-0293, separately reached a similar conclusion that reasonable support for a conclusion of substantial risk was evidenced for the glycidyl ethers examined in the respective cases. The basis for this conclusion is succinctly described by the present submitter:

> "Since our safety information indicates that under some conditions of exposure this mixture (of glycidyl ethers) can be absorbed, become systemic, and reach gonadal tissue, we conclude that the additional results of the mutagenicity battery support the conclusion that the mixture may present substantial risk to human health."

a) The submitter should be requested to send full copies of the results, including protocols and data, from the studies cited in this submission.

b) A copy of this submission and status report should be transmitted to TRDB, OSHA, NIOSH,CPSC, and OWWM. Because of the involvement of OE and OGC in 8EHQ-0279-0213, they, as well as the involved companies, should also receive copies.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 14 [illegible]

8EHQ-0779-0294
Page 1 of 2

DATE: Revised (May 28, 1980)

SUBJECT: Status Report* 8EHQ-0779-0294

Approved ____

Revision Needed ____

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division, OTE

Submission Description

Texaco, Inc. has submitted preliminary results from several in vitro mutagenicity studies of morpholine (CAS No. 110-91-8). The chemical was found to produce a dose-dependent mutagenic effect in a mouse fibroblast assay. However, the submitter states that negative results obtained from other in vitro assays (mouse lymphoma assay and Ames test) indicate that morpholine is not a mutagen. The submitter also reports that the data from a sister chromatid exchange assay were inconclusive and that this study will be repeated.

Ths submitter expresses concern that the positive mouse fibroblast assay results may have been influenced by the presence of nitrites or nitrates in the nutrient, which in combination with morpholine could lead to the formation of N-nitrosomorpholine.

Submission Evaluation

Without complete copies of the test protocols and data from the cited studies of morpholine, a full evalation of the submitted mutagenicity information is not possible at this time.

The submitter's concern regarding the possible presence or in situ formation of N-nitrosomorpholine is valid and warrants the planned additional examinations.

Current Production and Use

The review of the production range (includes importation volumes) statistics for morpholine (CAS. No. 110-91-8), which is listed in the initial TSCA Inventory, has shown that between 100 thousand and 1 million pounds of this chemical were produced/imported in 1977.**/

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

A FORM 1320-6 (REV. 3-76)

The submitter reports that morpholine is used as a corrosion inhibitor, especially in steam boiler systems; an emulsifier for cosmetics, rubless waxes and polishes; separating agent for volatile amines; an intermediate in the manufacture of optical brighteners, an intermediate for textile lubricants, softening agents, adjuvants, whitening agents, sizing emulsifiers, rubber vulcanization accelerators, antioxidants, surface-active agents, plasticizers, viscosity improvers, insecticides, fumigants, herbicides, dyes, catalysts, bactericides, analgesics, anesthetics,and other physiologically active agents.

Comments/Recommendations

The submitter reports that "in addition to the usual handling instructions on the material safety data sheets covering morpholine, there is an added statement, 'Do not use sodium nitrite or other nitrosating agents in formulations containing this product. Suspected cancer-causing nitrosamines could be formed'."

The existing Chemical Hazard Information Profile (CHIP) on morpholine has been scheduled for updating.

a) The submitting company should be requested to provide full copies of the test protocols and data from the studies cited in its submission.

b) A copy of this submission and status report should be transmitted to NCI, OSHA, NIOSH, CPSC, OWWM, and OPP.

**/This production range information does not include any production/importation data claimed as confidential by the person(s) reporting for the TSCA Inventory, nor does it include any information which would compromise Confidential Business Information. The data submitted for the TSCA Inventory, including production range information, are subject to the limitations contained in the Inventory Reporting Regulations (40 CFR 710).

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 20 1979

8EHQ-0779-0295
Page 1 of 2

DATE: Revised (May 28, 1980)

SUBJECT: Status Report* 8EHQ-0779-0295

Approved ____________

Revision
Needed ____________

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division, OTE/OTS

Submission Description

The IBM Corporation has submitted the summarized results of a skin absorption study in rabbits using Direct Black 38 Dye (CAS No. 1937-37-7) which was radioactively labelled with Carbon 14 in the biphenyl moiety. The submitter states that the preliminary data suggest that the dye or a portion of its molecule penetrates the unbroken skin or experimental animals and appears later in the urine and feces.

Submission Evaluation

The summarized preliminary results reported in this submission on Direct Black 38 Dye are very significant and raise definite concern. The dye, or a portion of the dye molecule, was rapidly absorbed from the unbroken skin. Thirty percent of the applied dose was absorbed and excreted within the first 24 hours and by the sixth day of this study 90% of the applied dose had been recovered in the urine and feces. The remaining 10% of the applied dose, if absorbed, may still have been in the body. The long sojourn in the body suggests binding to blood plasma proteins and possibly to other tissue proteins. Some benzidine dyes, used in chemotherapy exhibit this type of prolonged binding to a variety of blood and tissue proteins. The binding is unusual in that serum proteins bound to the dye no longer provoke an anaphylactic reaction in sensitized animals. (An example of a dye which exhibits this type of prolonged binding is Suramin. Although it is not technically a benzidine dye, its properities *in vivo* so closely resemble benzidine dyes that many pharmacologists have considered it as belonging to that group.)

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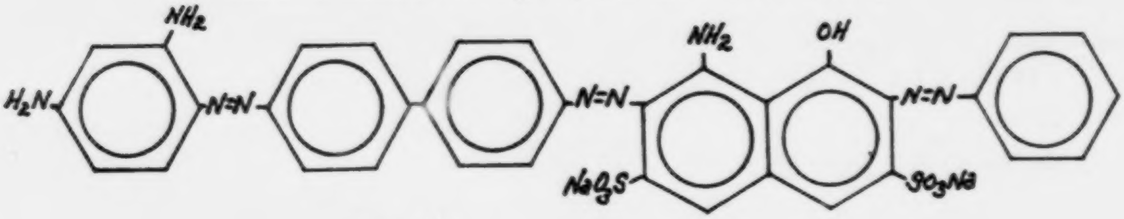
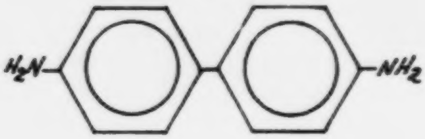
*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

The significant metabolite of Direct Black 38 Dye appears to be benzidine which has been well established as a urinary bladder carcinogen in humans.

Direct Black 38 Dye (CAS No. 1937-37-7)



Benzidine



Current Production and Use

According to the most recent published data, there is only one manufacturer of Direct Black 38 Dye in the United States. It is estimated that 700,000 to 800,000 pounds of this dye was produced in the U.S. in 1978. The U.S. imported approximately 170,000 pounds of Direct Black 38 Dye in 1978.

Direct Black 38 Dye is used in some textile dyes, aqueous inks, biological stains, plastics, wood-flour (used as a resin filler), wood stains, leather goods stains, and typewriter ribbons.

Comments/Recommendations

a) The submitter should be requested to provide a full copy of the final report from this skin absorption study including test protocols and data. In addition, the submitting company should be requested to provide information regarding its uses of Direct Black 38 Dye.

b) It is recommended that Direct Black 38 Dye be considered a candidate for a Section 8(a) rule.

c) This submission and status report should be transmitted to NIOSH, OSHA, CPSC, FDA, OWWM, ITC, NCI, and CREB.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 11 1979

DATE: Revised (May 28, 1980)

8EHQ-0779-0296
Page 1 of 2

SUBJECT: Status Report* 8EHQ-0779-0296

Approved ______

Revision Needed ______

FROM: Frank Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division

Submission Description

Cincinnati Milacron Chemicals, Inc. has reported the results of several acute animal toxicity and irritation studies of ethyltriphenylphosphonium acid acetate, tetrabutylphosphonium acid acetate, benzyltriphenylphosphonium chloride, and ethyltriphenylphosphonium iodide.

Submission Evaluation

These aryl and alkyl phosphonium compounds would be expected to have the typical pharmacological actions of quaternary ammonium compounds. These effects are mainly cholinergic stiumlations manifested by: 1) paralysis of skeletal muscle, the most serious effect involving the muscles of respiration leading to difficulty in breathing and death; 2) red ("bloody") tears, i.e., chromadacryorrhea; 3) contracation of smooth muscles leading to diarrhea and an altered urinary pattern; 4) altered blood pressure (usually lowering); 5) altered cardiac rhythm. The submitted toxicity studies show that the subject chemicals exhibit at least the first three of these pharmacological actions.

A more adequate estimation of the relative toxicity of these compounds would be:

	LD_{50}	Relative Toxicity
benzyltriphenylphosphonium chloride	1.1×10^{-4}M	1
ethyltriphenylphosphonium iodide	1.9×10^{-4}M	0.59 (2/3)

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

	LD_{50}	Relative Toxicity
ethyltriphenylphosphonium acid acetate	3.75×10^{-4}M	0.31 (1/3)
tetrabutylphosphonium acid acetate	2.14×10^{-3}M	0.05 (1/20)

Current Production and Use.

A review of production range (includes importation volumes) statistics for benzyltriphenylphosphonium chloride (CAS No. 1100-88-5) as listed in the initial TSCA Inventory (1977) has shown that between 1,000 and 10,000 pounds of this chemical was reported produced/imported in 1977. This production range information does not include any production/importation data claimed as confidential by the person(s) reporting for the TSCA Inventory, nor does it include any information which would compromise Confidential Business Information.

A review of production range (includes importation volumes) statistics for ethyltriphenylphosphonium iodide (CAS No. 4736-60-1); tetrabutylphosphonium acid acetate (CAS No. 17786-43-5); ethyltriphenyphosphonium acid acetate (CAS No. 35835-94-0) as listed in the initial TSCA Inventory (1977) has shown that no 1977 production/importation was reported or that all of the production range data reported was claimed as confidential by the manufacturer(s) and importer(s) and cannot be disclosed. (Section 14(a) of the TSCA, U.S.C. 2613 (a)).

The data submitted for the TSCA Inventory, including production range information, are subject to the limitations contained in the Inventory Reporting Regulations (40 CFR 710).

According to this 8(e) submission, these chemicals are sold by the submitter for use as catalysts and stabilizers in quantities (of all products combined) under 100,000 pounds annually.

Comments/Recommendations

(a) The submitting company states that their customers have been informed of the reported toxicity and the safe handling procedures for these chemicals. This submission and status report should be transmitted to OSHA and NIOSH.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 31 1979

8EHQ-0779-0297
Page 1 of 2

Approved ____________

Revision Needed ____________

DATE: Revised (May 28, 1980)

SUBJECT: Status Report* 8EHQ-0779-0297

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division, OTE (TS-792)

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Submission Description

The Gulf Mineral Resources Company has submitted a summary of preliminary results from an ongoing mouse skin painting study of solvent refined coal (SRC-II) heavy distillate (CAS No. 68410-07-1). The results indicate that on repeated (three times per week) dermal exposures to 2.4 mg of SRC II heavy distillate, a 20-25% incidence of skin tumors was observed after 247 days. This incidence is reported to increase to 100% at a dose level of 23.6 mg after 147 days.

The submitter also reports that acetone, which was used as the sample diluent, has a profound effect on the distribution of the SRC II heavy distillate in the skin, and may therefore affect the tissue absorption and metabolism of that tested material. The submitter also states that this "solvent effect obviously would not be present in usual human exposure routes."

Submission Evaluation

The role of the acetone vehicle in the carcinogenic action of SRC-II heavy distillate can only be surmised until the composition of the product is known. Does this product contain polynuclear aromatic hydrocarbons? It is doubtful that an adjuvant action of acetone determines whether SRC-II heavy distillate will or will not be carcinogenic; however, it may determine the potency.

Current Production and Use

A review of the production range (includes importation volumes) statistics for SRC II heavy distillate (CAS No. 68410-07-1) as listed in the initial TSCA Inventory (1977) has shown that between 100,000 and 1,000,000 pounds of this chemical were produced/imported in 1977. This production range information does not include any production/importation data claimed as confidential by the person(s) reporting for the TSCA inventory, nor does it include any information which would compromise Confidential Business Information. The data submitted for the TSCA Inventory, including production range information, are subject to the limitations contained in the Inventory Reporting Regulations (40 CFR 710).

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

The submitter states that SRC-II heavy distillate is not envisioned as being produced as a separate item in commerce, but rather as a component of a fuel oil product.

Comments/Recommendations

(a) The submitter should be requested to provide full copies of the final results from this skin painting study including test protocols and data. In addition, the submitter should be asked to provide any available data describing the chemical composition of SRC-II heavy distillate.

(b) A copy of the submission and status report should be transmitted to OSHA, NIOSH, OWWM, and ORD. A copy of the status report should be transmitted to the DOE contact cited in the submission.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 6 [illegible]

DATE: Revised (May 28, 1980)

SUBJECT: Status Report* 8EHQ-0779-0299

FROM: Walter W. Kovalick, Jr., Director
Program Integration Division (TS-793)

TO: Joseph J. Merenda, Director
Assessment Division (TS-792)

8EHQ-0779-0299
Page 1 of 1
Approved GM
Revision Needed

Submission Description

On July 10, 1979, an FMC Corporation official reported that approximately 1,000 pounds of Furadan® 10G was released by an "aerial applicator" into the air over a farm pasture in Harrisonburg, VA. The incident was reported by telephone to Lynda Young, EPA Region III. EPA headquarters received a follow-up letter to the telephone incident on July 23, 1979.

Submission Evaluation

Furadan® 10G is a pesticide registered by EPA (No. 279-2712 AA) according to the Federal Insecticide, Fungicide and Rodenticide Act. As was mentioned in the follow-up letter, Furadan® 10G is not subject to the reporting requirements of section 8(e), because it is not a chemical substance as defined by the Toxic Substances Control Act.

Comments/Recommendations

This incident was referred to the Office of Pesticide Programs for follow-up.

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 22 1979

DATE: Revised (May 28, 1980)

SUBJECT: Status Report* 8EHQ-0879-0300

FROM: Walter W. Kovalick, Jr., Director
Program Integration Division (TS-793)

TO: Joseph J. Merenda, Director
Assessment Division (TS-792)

8EHQ-0879-0300
Page 1 of 1
Approved ____
Revision Needed ____

Submission Description

Raccoon Valley Truck Stop, Tennessee, Spill of Acrylonitrile

Cincinnati Milacron Chemicals, Inc. reported that on July 23, 1979, 30 to 35 gallons of acrylonitrile were spilled from a truck enroute from Cincinnati, Ohio to Salisbury, NC. The acrylonitrile leaked from a damaged drum. The submitter estimates that most of the spill probably occurred at the Raccoon Valley Truck Stop where the leak was detected. Immediately after the spill, a hazardous material recovery team, local police, civil defense, DOT and Cincinnati Milacron employees assisted in the clean-up and recovery. On July 24, the spill was reported to the National Response Center which then contacted EPA Region IV, the Coast Guard's Office of Hazardous MaterialS, the Bureau of Motor Carrier Safety, and the National Transportation Safety Board.

Submission Evaluation

Acrylonitrile is an extreme irritant to the skin; it is also toxic when inhaled. However, no injuries or illnesses were reported to have resulted from this incident.

Comments/Recommendations

Due to the fact that a small quantity of acrylonitrile was released which was immediately cleaned up, no further action is indicated either by the State, EPA or other Federal agencies.

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 30 [illegible]

8EHQ-0879-0301
8EHQ-0879-0301 Supplement

DATE: Revised (May 28, 1980)

Page 1 of 2

SUBJECT: Status Report* 8EHQ-0879-0301
8EHQ-0879-0301 Supplement

Approved ______

Revision Needed ______

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division, OTE

Submission Description

Both the initial and supplemental submissions (provided by the Union Oil Company of California and Texaco, Inc., respectively) present final results from the same trade-association sponsored mutagenicity study of Number 2 Home Heating Oil. The submitters report that the results indicate that this fuel oil had the ability to produce mutagenic effects in the following test systems: in vitro mouse lymphoma test (with and without metabolic activation); in vivo rat bone marrow cytogenetics test (via oral administration); and Ames test (with and without metabolic activation). The conducting laboratory had judged that the results of the Ames test were equivocal based on the lack of a dose-related effect; the other test results were judged positive for mutagenicity.

Submission Evaluation

Number 2 Home Heating Oil did evidence mutagenic potential in all of the performed tests. Both with and without metabolic activation, this oil was found to increase the mutation frequency in several bacterial strains used in the Ames test and, in the cultured mammalian cells in the mouse lymphoma assay. Via oral administration, Number 2 Home Heating Oil was found to increase the number of chromosomal aberrations (e.g. chromatid breaks) in the in vivo rat bone marrow cytogenetics test.

Current Production and Use

According to information provided in the supplemental submission, Number 2 Home Heating Oil is a mixture of virgin and catalytically cracked petroleum stocks (CAS Numbers 64741-44-2 and 64741-

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

A review of the production range (includes importation volumes) statistics for Straight Run Middle Distillate (CAS. No. 64741-44-2) which is listed in the initial TSCA Inventory has shown that approximately 100 billion pounds of this chemical were produced/imported in 1977.**/

A review of the production range (includes importation volumes) statistics for Light Catalytic Cracked Distillate (CAS. No. 64741-59-9) which is listed in the initial TSCA Inventory has shown that between 53 billion and 90 billion pounds of this chemical were produced/imported in 1977.**/

Comments/Recommendations

The Agency has previously received and evaluated a section 8(e) submission which indicated that Number 2 Burner Fuel, also composed of virgin and catalytically cracked stocks, had caused malignant skin neoplasms following lifetime dermal application to mice (8EHQ-0778-0215).

(a) Both submitters should be requested to describe the actions taken by their companies in light of the submitted toxicity information to reduce or eliminate exposure to this fuel and/or to warn workers and purchasers of this new toxicity information.

(b) Copies of these submissions and status report should be transmitted to DOE, OSHA, NIOSH, and OWWM.

**/This production range information does not include any production/importation data claimed as confidential by the person(s) reporting for the TSCA Inventory, nor does it include any information which would compromise Confidential Business Information. The data submitted for the TSCA Inventory, including production range information, are subject to the limitations contained in the Inventory Reporting Regulations (40 CFR 710).

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 30 1980

DATE: Revised (May 28, 1980)

8EHQ-0879-0304
Page 1 of 2

SUBJECT: Status Report* 8EHQ-0879-0304

Approved

FROM: Frank Kover, Chief
Chemical Hazard Identification Branch

Revision
Needed

TO: Joseph J. Merenda, Director
Assessment Division, OTE

Submission Description

The submission consists of a report from a BF Goodrich Company employee who states that numerous cases of dermatitis and several cases of nausea and dizziness have been observed in co-workers exposed to a number of organic solvents, treated fabrics, and cements used in the workplace. A company-prepared form entitled "Toxic Substances Control Act Substantial Risk Report" was used by the employee in reporting the information to the EPA.

Submission Evaluation

In the absence of more detailed information, it is not possible at this time to determine which chemical or combination of chemicals is directly responsible for the observed adverse health effects. Many organic solvents are known to be irritating to the skin and can cause dizziness and nausea if inhaled.

The information pertaining to the inadequate safety precautions taken and the adverse health effects observed following exposure to chemicals in the workplace would be of interest to OSHA and NIOSH.

Comments/Recommendations

According to Part V and Part V(a) of the March 16, 1978, section 8(e) policy statement (43 FR 11110) the Agency considers the effects for which substantial-risk information must be reported to include: "Any instance of cancer, birth defects, mutagenicity, death, or serious or prolonged incapacitation, including the loss of or inability to use a normal bodily function with a consequent Few) chemicals(s) is strongly implicated."

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

In general, the Agency does not consider the observation of certain symptoms (such as dermal ailments or nausea) by themselves to be reportable under section 8(e) of TSCA. However, in certain cases there is an obligation to report such effects under section 8(e) if they are suspected of being precursor symptoms to more serious human health effects.

Inquiry was made of the NIOSH Health Hazard Evaluation Program, operating out of Cincinnati, Ohio, to determine what assistance the program could provide in cases such as this. A representative of the program forwarded copies of a NIOSH booklet (attached) which describes the program. The booklet specifies that before NIOSH can act, a request for a health hazard evaluation must be made by one of the following: an employer representative; an authorized representative of the employees for collective bargaining purposes; an authorized representative of two or more employees; or one of three or less employees in the workplace. The booklet also contains a form which can be used to request a workplace evaluation.

a) A copy of the booklet on NIOSH's Health Hazard Evaluation Program and a copy of the March 16, 1978 section 8(e) Policy Statement should be sent to the submitter. The submitter's employer should also receive a copy of the status report.

b) Copies of the submission, status report, and followup letter should be sent to OSHA and NIOSH. PID should also receive a copy of this package.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1 4 1980

8EHQ-0979-0305
8EHQ-1079-0305 Supplement
Page 1 of 3

DATE: Revised (May 28, 1980)

SUBJECT: Status Report* 8EHQ-0979-0305
and 8EHQ-1079-0305 (Supplement)

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division, OTE

Approved ____________

Revision
Needed ____________

Submission Description

The two submitters (the Union Carbide Corporation and the Celanese Corporation) present somewhat differing assessments of the results from a preliminary pathologic examination of rats sacrificed at the termination of a 24-month chronic inhalation toxicity study of ethylene oxide (CAS No. 75-21-8) at concentrations of 10, 33, and 100 ppm. The study is being co-sponsored by 12 companies. In the initial submission, Union Carbide states that "an assessment of the preliminary examination...has led to a suspicion that at the highest concentration (100 ppm) ethylene oxide may have increased the incidence of [leukemia and] tumors in certain organs over that seen in similar organs in two control groups of rats." At a later point in the submission the incidence of tumors and leukemia in the highest group was characterized as being "statistically significant." The initial submission also reported a statistically significant increase in mortality at the 100 ppm level over that seen in controls. In the supplemental submission, Celanese reported similar findings for the 100 ppm group but went on to state that "at the mid-exposure level (33 ppm) a higher incidence of subcutaneous skin masses or nodules and a higher mortality rate was observed." It was not stated by the supplemental submitter whether the findings in the 33 ppm group were statistically significant.

Submission Evaluation

An increased incidence of lesions, particularly neoplasms, over that which is known to occur spontaneously is always of concern. The assumption is that various factors (e.g., chemicals, viral infections, etc.) can diminish the organism's ability to control the development of such neoplasms. This lack of control results in the reappearance in the organism of embryonic and fetal development processes (e.g., appearance of alpha-feto protein during tumor development; appearance of placental enzymes in men and non-pregnant women during development of cancer; reappearance of fetal liver enzymes in mature rats which have been administered carcinogens).

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

On the basis of the preliminary pathologic findings, ethylene oxide appears to have had oncogenic activity in the study. Final assessment of this study will have to await the final laboratory and pathology report. The supplemental submitter's contention that "33 ppm was a 'minimal effect level' and that 10 ppm was a no effect level" appears somewhat premature in light of the preliminary nature of the available data.

Current Production and Use

The annual production of ethylene oxide was, according to secondary sources consulted, greater than 4 billion pounds in both 1975 and 1976.

A review of the production range (includes importation volume) statistics for ethylene oxide (CAS No. 75-21-8) which is listed in the initial TSCA Inventory (1977) has shown that between 1.46 billion and 5.36 billion pounds of this chemical were produced/imported in 1977. This production range information does not include any production/importation data claimed as confidential by the person(s) reporting for the TSCA Inventory, nor does it include any information which would compromise Confidential Business Information. The data submitted for the TSCA Inventory, including production range information, are subject to the limitations contained in the Inventory Reporting Regulations (40 CFR 710).

Ethylene oxide is used as an intermediate in the production of ethylene glycol, acrylonitrile, ethanolamine, glycol ether, and non-ionic surfactants. It is also used as a sterilant and fumigant.

Comments/Recommendations

The information contained in these submissions is indicative of the oncogenicity of ethylene oxide but is not sufficiently complete to assess, at this time, the oncogenic or carcinogenic potential of ethylene oxide under the conditions of this study.

The initial submission states that the "detailed microscopic examination of the tissues, recording of results and drawing of conclusions to the experiment will require an additional year.

The full report will be submitted when it issues."

(a) The initial submitter states that a copy of his submission has been sent to NIOSH, OSHA, NCI, and ACGIH. However, in order to insure completeness, a copy of this status report and both submissions should be transmitted to NIOSH, OSHA, NCI, ACGIH, CPSC, FDA, ITC, OAQPS, OPP, and TRDB/AD.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

30 1980

8EHQ-0979-0306
8EHQ-1179-0316
Page 1 of 3
Approved
Revision
Needed

DATE: Revised (May 28, 1980)

SUBJECT: Status Report* 8EHQ-0979-0306
8EHQ-1179-0316

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division, OTE

Submission Descriptions

Submissions 8EHQ-0979-0306 and 8EHQ-1179-0316 (received from the Exxon Corporation and the Exxon Company, U.S.A., respectively) present summaries of preliminary results from ongoing mouse dermal carcinogenicity assays of experimental coal-derived fuel oils. Both submitters state that the preliminary results indicate that the tested substances (listed below) have caused tumors in mice "within time periods which indicate high carcinogenic potency."

In providing these preliminary results under section 8(e) both submitters report that although the findings are "qualitatively consistent with the known carcinogenic potential of high-boiling, coal-derived materials", they have not been able to establish that the published scientific literature contains specific data on these particular fractions.

8EHQ-0979-0306

1. Experimental pyrolysis fuel oil fraction derived from East Texas lignite (untreated; from test gasification).
2. Experimental pyrolysis fuel oil fraction derived from Arkansas lignite (untreated; from test pyrolysis).
3. Illinois bituminous coal-derived heavy fuel oil (from direct liquefaction tests).
4. Wyoming sub-bituminous coal-derived distillate fuel oil (from direct liquefaction tests).

8EHQ-1179-0316

5. Experimental pyrolysis fuel oil fraction from East Texas lignite (hydrotreated; from test gasification).

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

Submission Evaluation

In the absence of submitted chemical analyses, it could be presumed that all of the tested coal-derived fractions contain polynuclear aromatic hydrocarbons and triterpanes. Triterpanes, which are structurally similar to important human steroid hormones (e.g. pregnanes), may also exhibit certain biological activities.

Of the samples tested, the untreated pyrolysis fuel oil fraction derived from East Texas lignite (sample 1. above) appears to be the most potent oncogen. The other samples, although less potent, do exhibit oncogenic activities in these ongoing studies.

Current Production and Use

A search of the master inventory file has shown that these experimental coal-derived fuel oils are not listed on the intial TSCA Inventory. There are relatively few entries on the TSCA Inventory which are "coal-specific" and those that are listed, are non-specific with regard to the geographical source of the coal.

It is assumed that these experimental coal-derived fractions are intended for use as feedstocks for subsequent distillation and treatment in a refining plant. The end-uses of the resulting refinery products (i.e. synthetic natural gas, gasoline, solvents, etc.) are expected to be similar to those for petroleum oil products.

Comments/Recommendations

Status reports have been prepared for a number of section 8(e) submissions received on synthetic and petroleum fuels: 8EHQ-0029, 0030, 0044, 0082, 0083, 0117, 0148, 0212, 0215, 0216, 0217, 0238, 0240, 0247, 0252, 0253, 0297, and 0301. (These numbers represent the last four digits of the Document Control Officer assigned numbers.)

a) Both submitters report that the studies are continuing and that the Agency will be advised of the outcome. However, at this time, the submitters should be requested to provide full copies of the reported interim results including test protocols and any available pathology data from these ongoing mouse dermal carcinogenicity studies. In addition, the submitters should be requested to provide the CAS numbers (if known) and any available data from chemical analyses of these coal-derived fractions.

b) The submitters should also be requested to describe any actions taken by their companies, in light of this toxicity information, to reduce or eliminate exposure to these chemicals and/or to warn workers and purchasers of this new toxicity information.

c) Copies of these submissions and status report should be transmitted to DOE, OSHA, NIOSH, OWWM, and ORD.

d) CHIB will review the additional data requested, revise this Status Report as appropriate, and recommend further followup assessment if warranted.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

30 1980

8EHQ-0979-0310
Page 1 of 2

Approved

Revision
Needed

DATE: Revised (May 28, 1980)

SUBJECT: Status Report* 8EHQ-0979-0310

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division, OTE

Submission Description

The Aerojet-General Corporation reports that eleven chlorinated organic chemicals have been identified as groundwater contaminants at a site outside Sacramento, California. The submitted chemical analyses show that trichloroethylene, 1,1,1-trichloroethane, chloroform, carbon tetrachloride, trans-1,2-dichloroethene (incorrectly spelled in the submitted table), tetrachloroethylene, 1,1-dichloroethane, 1,1-dichloroethylene, 1,2-dichloroethane, chlorobenzene, and 1,1,2-trichloroethane are present in varying concentrations in several different domestic and industrial well water samples and test borings. The submitter states that"the adverse effects and the extent of the risk involved are unknown." In addition, the submission reports that evidence that the submitter and/or a near-by company are the source of this groundwater contamination has not been shown.

Submission Evaluation

With one exception (chlorobenzene) the contaminating chemicals are chlorinated derivatives of methane, ethane, and ethylene. Several of these are carcinogens. All of the reported chemicals, including chlorobenzene, cause liver injury. Most of the chemicals also cause kidney injury. Such closely related chemical compounds may have the potential for synergism.

Current Production and Use

Based on the nature of this submission, a review of the current production and uses of the subject chemicals is not necessary at this time.

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

Comments/Recommendations

Region IX has placed this site of contamination on the list of Uncontrolled Hazardous Waste Sites. It is the concensus of Region IX and the State of California that this site presents a potential hazard to human health and the environment.

A report (FRL-756-4) on the human effects caused by exposure to chemical contaminants in drinking water has been prepared by the National Academy of Sciences in accordance with the Safe Drinking Water Act (P.L. 93-523).

EPA has recently published (November 29, 1979) a final rule which establishes a maximum contaminant level for total trihalomethanes (THMs), including chloroform, in drinking water of 100 ppb (40 CFR 68624). This requirement will apply in two years to water systems serving communities of 75,000 or more and to systems serving 10,000-75,000 in four years.

(a) Follow-up activities by state and local agencies concerning this reported contamination will be monitored by Region IX. CHIB has requested to be informed of any future developments by way of status reports prepared by the Hazardous Materials Branch, Region IX.

(b) A copy of this status report should be transmitted to the Region IX Office (Hazardous Materials Branch). A copy of the original submission was transmitted previously to that branch by CHIB.

(c) Copies of the submission and status report should be transmitted to OWWM, SAD/OPII, PID/OPII, CREB, and TRDB.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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8EHQ-0979-0311
Page 1 of 3

DATE:

SUBJECT: Status Report* 8EHQ-0979-0311

Approved 4/22/80

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

Revision Needed

TO: Joseph J. Merenda, Director
Assessment Division, OTE

Submission Description

In a letter dated January 15, 1980, the submitting company withdrew its claims of confidentiality for this notice.

PPG Industries, Inc. has reported that a chemical mixture (see Table I below), when applied to the eyes of rabbits, caused a clouding of the corneas within 20 seconds. Subsequent water rinsing of the affected eyes for one minute did not alleviate the condition; cloudiness and several ulcers of the corneas were still evident 14 days following application of the mixture. In addition, the submitter reports that two previous laboratory studies have demonstrated that diallyl diglycol carbonate alone does not cause demonstrable eye irritation or other abnormality.

With regard to the nature and extent of the risk involved the submitting company states:

> "Based upon the information reported..., the nature of the risk is immediate and irreversible changes (opacity and ulceration) to the corneas of rabbits. These lesions would be expected to indicate a partial or total loss of visual function of the eye. The extent of the risk is limited by the fact that this mixture was in PPG Industries, Inc., research, was not manufactured and, to the best of the [submitter's] knowledge, has not been distributed."

TABLE I Chemical Mixture Components

75%	Diallyl diglycol carbonate	CAS No. 142-22-3
20%	Maleic anhydride	CAS No. 108-31-6
5%	Tungsten hexacarbonyl	CAS No. 14040-11-0
100 ppm	Hydroquinone monomethyl ether	CAS No. 150-76-5

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

Submission Evaluation

Maleic anhydride is the most likely substance in the mixture to produce rapid corneal opacity and ulceration. The Merck Index points out that maleic anhydride is a powerful irritant that can cause burns. The 1 minute post-application wash reported was inadequate (the Merck Index recommends at least a 15 minute wash). However, there is a possibility that the observed effects were due to a combination of two or more of the components in the tested mixture. Further studies would have to be conducted to better define the observed toxicity. The diallyl diglycol carbonate and tungsten hexacarbonyl alone might be somewhat irritating but they are not likely to be corrosive. Hydroquinone monomethyl ether is one of several monoalkyl ethers of hydroquinone that are used as antiseptics. A concentration of 100 ppm would not be likely to produce the observed rapid corneal opacity.

Current Production and Use

A review of the production ranges (includes importation volumes), for those mixture components which are listed in the initial TSCA Inventory, has shown the following amounts reported as produced/imported in 1977:

Chemical Name	Approx. Prod./Import.Range **/
Diallyl diglycol carbonate (CAS No. 142-22-3)	1 million to 10 million lbs.
Maleic anhydride (CAS No. 108-31-6)	100 million to 457 million lbs.
Hydroquinone monomethyl ether (CAS No. 150-76-5)	100 thousand to 1 million lbs.

A search of the master inventory file for tungsten hexacarbonyl (CAS No.14040-11-0) has shown that this chemical is not listed on the TSCA Inventory. Information on the production/importation volumes for this chemical could not be located in the secondary literature sources consulted.

Information on the actual/proposed uses of the chemical mixture was not provided in the submission. The mixture is apparently still in R & D.

**/ This production range information does not include any production/importation data claimed as confidential by the person (s) reporting for the TSCA Inventory, nor does it include any information which would compromise Confidential Business Information. The data submitted for the TSCA Inventory, including production range information, are subject to the limitations contained in the Inventory Reporting Regulations (40 CFR 710).

Comments/Recommendations

(a) The submitting company should be requested to describe the actions it has taken, in light of the reported toxicity information, to warn workers and/or to reduce or eliminate exposure to the subject chemical mixture and its components.

(b) The Agency should transmit a copy of this submission and status report to OSHA and NIOSH. Because tungsten hexacarbonyl was not located on the master TSCA Inventory, the Premanufacturing Review Division/OCC should also receive copies of this information.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 2 1980

8EHQ-1079-0312
Page 1 of 2

DATE: Revised (May 28, 1980)

SUBJECT: Status Report* 8EHQ-1079-0312

Approved CM

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

Revision
Needed

TO: Joseph J. Merenda, Director
Assessment Division, OTE

Submission Description

The Exxon Company, U.S.A. has submitted a summary of the final results from a 12-week inhalation toxicity study of ISOPAR C and VARSOL 40 solvents in male and female rats. Evidence of kidney damage is reported for male rats exposed to the solvents.

Submission Evaluation

Both ISOPAR C and VARSOL 40 appear to produce typical toxic nephrosis (degeneration of the epithelial cells of the kidney tubules without damage to the basement membrane). Mercury, dichromate, uranium, chloroform, carbon tetrachloride, dioxane, and many other chemicals produce similar lesions in the kidney.

Current Production and Use

The submitter states that ISOPAR C is an isoparaffinic hydrocarbon solvent (CAS No. 64741-66-8).

A review of the production range (includes importation) statistics for CAS No. 64741-66-8 (naptha (petroleum) light alkylate) which is listed in the initial TSCA Inventory (1979) has shown that between 8.7 billion and 27.3 billion pounds of this chemical were produced/imported in 1977.**

"ISOPAR" is a trademark for a group of high-purity paraffinic materials. These materials are used as odorless solvents,and reaction diluents, and are permitted under a number of FDA regulations for food-related applications.

The submitter states that VARSOL 40 (a mixture of aromatic, paraffinic, and napthenic hydrocarbons,) is not marketed in the U.S. However, VARSOL 40 is similar to VARSOL 1 which is distributed in commerce domestically. VARSOL 1, like VARSOL 40, is a mixture. The CAS No. of the petroleum hydrocarbon portion of VARSOL 1, exclusive of additives is 64742-88-7.

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

EPA FORM 1320-6 (REV. 3-76)

A review of the production range (includes importation volumes) statistics for CAS No. 64742-88-7 (solvent naptha(petroleum), medium aliphatic) as listed in the initial TSCA Inventory (1979) has shown that between 1.5 billion and 4.1 billion pounds of this chemical were produced/imported in 1977.**

"VARSOL" is a trademark for straight petroleum aliphatic solvents used as paint and varnish thinners, for dry cleaning, and for general plant machinery cleaning.

Comments/Recommendations

a) The submitter should be requested to provide a full copy of the final results including test protocols and data from the recently concluded 12-week inhalation toxicity studies of ISOPAR C and VARSOL 40 in rats.

b) The submitter should be requested to describe the actions taken by his firm based on this information to control exposure to the chemicals and/or to warn workers or purchasers of this new toxicity information.

c) Copies of this submission and status report should be transmitted to FDA, OSHA, NIOSH, CPSC, OANR, OCC/CAD, and OWWM.

**This production range information does not include any production/importation data claimed as confidential by the person(s) reporting for the TSCA Inventory, nor does it include any information which would compromise Confidential Business Information. The data submitted for the TSCA Inventory, including production range information, are subject to limitations contained in the Inventory Reporting Regulations (40 CFR 710).

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 15 1979

8EHQ-1079-0314
Page 1 of 3

DATE: Revised (July 30, 1980)

SUBJECT: Status Report* 8EHQ-1079-0314

Approved JM 7/31/80

Revision Needed

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division

Submission Description

The Chemical Industry Institute of Toxicology (CIIT) and several chemical manufacturers have provided the same summary report of interim sacrifice pathology results from a 24-month inhalation toxicity study of formaldehyde (CAS No. 50-00-0) in mice and rats. It is reported that nasal squamous cell carcinomas have been detected in three (3) of the rats sacrificed at the highest dose tested (15 parts per million). No squamous cell carcinomas of the nasal cavity have been observed by the performing laboratory in the exposed or control mice, nor in 480 control rats in this study. One other case of squamous cell carcinoma was observed in rats exposed to 6 parts per million. The summary report states, however, that this particular lesion differs from those reported at 15 ppm in that it appears to have arisen from the spindle-cell layer of the skin which makes the relationship of this neoplasm to formaldehyde exposure less clear.

Submission Evaluation

The reported findings of nasal squamous cell carcinomas in Fischer 344 rats appear to be highly significant as this particular type of lesion is not frequently observed. As the provided summary pathology reports note:

> "In two recently completed inhalation studies involving a total of 1920 Fischer 344 rats purchased from the same supplier, no similar cancer was observed. The same is true in two feeding studies involving 1680

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> rats. A survey of spontaneous lesions in 3,548 aging Fischer 344 rats of both sexes (Goodman et al., Toxicol. Appl. Pharmacol. 48:237-248, 1979) fails to mention squamous cell carcinoma originating from the nasal respiratory epithelium."

A description of the experimental protocols and complete copies of any interim sacrifice pathology data, at a minimum, would be necessary to permit further evaluation of the findings summarized by these submissions.

Current Production and Use

A review of the production range (includes importation volumes) statistics for formaldehyde (CAS. No. 50-00-0) which is listed in the initial TSCA Inventory, has shown that between 2 billion and 7.9 billion pounds of this chemical were reported as produced/imported in 1977.**/

Formaldehyde has uses in: urea and melamine resins; polyacetal resins; phenolic resins; ethylene glycol; pentaerythritol; hexamethylenetetramine; fertilizer dyes, medicine (disinfectant, germicide); embalming fluids; preservative; hardening agent; reducing agent, as in recovery of gold and silver; corrosion inhibitor in oil wells; durable-press treatment of textile fabrics; possible condensation to sugars and other carbohydrates for food use (experimental); industrial sterilant; treatment of grain smut.

Comments/Recommendations

(a) The Agency should request complete copies of the experimental protocols and full pathology data from all interim sacrifices to date from this inhalation toxicity study of formaldehyde in rats and mice.

**/ This production range information does not include any production/importation data claimed as confidential by the person(s) reporting for the TSCA Inventory, nor does it include any information which would compromise Confidential Business Information. The data submitted for the TSCA Inventory, including production range information, are subject to the limitations contained in the Inventory Reporting Regulations (40 CFR 710).

(b) The Agency should transmit a copy of these summarized interim pathology results and EPA status report to OSHA, NIOSH, FDA, CPSC, NCI, HUD, DOE, and the interagency formaldehyde workgroup.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

8EHQ-1079-0315
Page 1 of 3

DATE:

SUBJECT: Status Report* 8EHQ-1079-0315

Approved JM 4/17/80

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

Revision
Needed

TO: Joseph J. Merenda, Director
Assessment Division

Submission Description

The Standard Oil Company (Indiana) reports that an employee in its liquid polymerization unit had complained of "severe throat irritation and an alarming shortness of breath, with chest pain on occasion" from inhaling the combined vapors of (1) tri [mixed mono- and dinonylphenyl] phosphite and (2) thiodipropionate ester complex. The submitter also states that the employee claiming "substantial risk", had neither sought any medical attention from the company's medical department at the time of the alleged exposure, nor complains of any lasting effects.

In addition, the submitter reports that, although the above materials have been handled since before 1968, to the company's knowledge there have been no previous complaints other than "simple respiratory irritation." The submitter does state however, that if "any information that verifies any evidence of substantial risk" is received, the Agency will be informed immediately.

Submission Evaluation

Inhalation of irritants can lead to a constriction of the smooth muscle of the airways which would account for the reported difficulty in breathing, shortness of breath, and chestpain. Such narrowing of the airways would be caused by histamine, acetylcholine or norepinephrine. Respiratory tract irritants could cause the release of one or more of these substances from nerve endings or mast cells present in the tracheobronchial smooth muscle.

Current Production and Use

Due to the nature of the information contained in this submission, a review of the current production of the subject chemicals does not appear to be necessary at this time.

The chemicals are apparently used as stabilizers/inhibitors in certain rubber and/or plastic polymerization processes.

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Comments/Recommendations

It is the Agency's preliminary determination that the acute toxicity information, as presented in this submission, did not warrant being reported under section 8(e) of TSCA. The rationale for this preliminary determination is as follows:

> According to Part V of the March 16, 1978 "Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" (43 FR 11110), a substantial risk of injury to health is a risk of considerable concern because of (a) the seriousness of the effect... and (b) the fact or probability of its occurence." With regard to the seriousness of the effect, the Agency considers the human health effects for which substantial risk information must be reported to include "any instance of cancer, birth defects, mutagenicity, death or serious or prolonged incapacitation, including the loss of or inability to use a normal bodily function with a consequent relatively serious impairment of normal activities...." In addition, Part VI(2) further states that it is possible that effects less serious than those described above may be preliminary manifestations of those more serious effects and together with another triggering piece of information, constitute reportable information.

Therefore, because the human health effects reported in this submission do not appear to be serious and did not produce a prolonged incapacitation or serious impairment of normal activities, the Agency believes that the provided acute human toxicity information, when considered alone, did not warrant reporting under section 8(e) of TSCA.

With regard to the submitter's statement which concerns the reporting of obtained "information that verifies any evidence of substantial risk", the Agency believes that the following clarification is needed. The submitter should note that section 8(e) states that the information required for reporting is any information which reasonably supports a conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment. The Agency considers that reasonable support of a conclusion of substantial risk is not identical to the conlusion itself. The former typically occurs, and must be reported at an earlier stage. In addition, Part VI of the section 8(e) policy statement specifies that a "person is not to delay reporting until he obtains conclusive information that a substantial risk exists, but is to immediately report any evidence which 'reasonably supports' that conclusion. Such evidence will generally not be conclusive as to the substantiality of the risk...."

The Test Rules Development Branch/AD, with support from the Chemical Review and Evaluation Branch/AD and the Environmental and Health Review Divisions, is currently reviewing data received by the Agency pertaining to the Interagency Testing Committee (ITC) designated category "Aryl Phosphates." One of the chemicals described in this 8(e) submission is a tri[mono- and dinonyl phenyl]phosphite which can, by way of an oxidative pathway be converted to the phosphate. Therefore, an information copy of this status report and submission should be sent to TRDB/AD for possible consideration in the ongoing review of data on aryl phosphates.

a) The submitting company should be requested to describe any actions taken, in light of the submitted toxicity information, to warn workers and/or to reduce or eliminate exposure to the subject chemicals.

b) The Agency should transmit a copy of this submission and status report to OSHA and NIOSH.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 30 1980

8EHQ-1179-0316
8EHQ-0979-0306
Page 1 of 3

Approved ____

Revision Needed ____

DATE: Revised (May 28, 1980)

SUBJECT: Status Report* 8EHQ-0979-0306
8EHQ-1179-0316

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division, OTE

Submission Descriptions

Submissions 8EHQ-0979-0306 and 8EHQ-1179-0316 (received from the Exxon Corporation and the Exxon Company, U.S.A., respectively) present summaries of preliminary results from ongoing mouse dermal carcinogenicity assays of experimental coal-derived fuel oils. Both submitters state that the preliminary results indicate that the tested substances (listed below) have caused tumors in mice "within time periods which indicate high carcinogenic potency."

In providing these preliminary results under section 8(e) both submitters report that although the findings are "qualitatively consistent with the known carcinogenic potential of high-boiling, coal-derived materials", they have not been able to establish that the published scientific literature contains specific data on these particular fractions.

8EHQ-0979-0306

1. Experimental pyrolysis fuel oil fraction derived from East Texas lignite (untreated; from test gasification).
2. Experimental pyrolysis fuel oil fraction derived from Arkansas lignite (untreated; from test pyrolysis).
3 Illinois bituminous coal-derived heavy fuel oil (from direct liquefaction tests).
4. Wyoming sub-bituminous coal-derived distillate fuel oil (from direct liquefaction tests).

8EHQ-1179-0316

5. Experimental pyrolysis fuel oil fraction from East Texas lignite (hydrotreated; from test gasification).

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

EPA FORM 1320-6 (REV. 3-76)

Submission Evaluation

In the absence of submitted chemical analyses, it could be presumed that all of the tested coal-derived fractions contain polynuclear aromatic hydrocarbons and triterpanes. Triterpanes, which are structurally similar to important human steroid hormones (e.g. pregnanes), may also exhibit certain biological activities.

Of the samples tested, the untreated pyrolysis fuel oil fraction derived from East Texas lignite (sample 1. above) appears to be the most potent oncogen. The other samples, although less potent, do exhibit oncogenic activities in these ongoing studies.

Current Production and Use

A search of the master inventory file has shown that these experimental coal-derived fuel oils are not listed on the intial TSCA Inventory. There are relatively few entries on the TSCA Inventory which are "coal-specific" and those that are listed, are non-specific with regard to the geographical source of the coal.

It is assumed that these experimental coal-derived fractions are intended for use as feedstocks for subsequent distillation and treatment in a refining plant. The end-uses of the resulting refinery products (i.e. synthetic natural gas, gasoline, solvents, etc.) are expected to be similar to those for petroleum oil products.

Comments/Recommendations

Status reports have been prepared for a number of section 8(e) submissions received on synthetic and petroleum fuels: 8EHQ-0029, 0030, 0044, 0082, 0083, 0117, 0148, 0212, 0215, 0216, 0217, 0238, 0240, 0247, 0252, 0253, 0297, and 0301. (These numbers represent the last four digits of the Document Control Officer assigned numbers.)

a) Both submitters report that the studies are continuing and that the Agency will be advised of the outcome. However, at this time, the submitters should be requested to provide full copies of the reported interim results including test protocols and any available pathology data from these ongoing mouse dermal carcinogenicity studies. In addition, the submitters should be requested to provide the CAS numbers (if known) and any available data from chemical analyses of these coal-derived fractions.

b) The submitters should also be requested to describe any actions taken by their companies, in light of this toxicity information, to reduce or eliminate exposure to these chemicals and/or to warn workers and purchasers of this new toxicity information.

c) Copies of these submissions and status report should be transmitted to DOE, OSHA, NIOSH, OWWM, and ORD.

d) CHIB will review the additional data requested, revise this Status Report as appropriate, and recommend further followup assessment if warranted.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

8EHQ-1179-0317
Page 1 of 3

DATE:

SUBJECT: Status Report* 8EHQ-1179-0317

Approved JM 4/2/80

Revision Needed

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division/OTE

Submission Description

The FMC Corporation has determined that the n-octanol/water partition coefficients for certain aryl phosphates are in excess of 25,000 (see Table 1 below). According to Part V(b)(2) of the March 16, 1978, TSCA Section 8(e) policy statement (43 FR 11110), the finding of an n-octanol/water partition coefficient greater than 25,000 is to be reported to EPA when the subject chemical has potential for widespread exposure and can cause any non-trivial adverse effect. In submitting this type of physical/chemical information under section 8(e), the company states:

> "Because there may be a 'potential for widespread exposure', and because there exists possibility of 'non-trivial adverse effects' (e.g., toxicity to fish) this information may constitute 'substantial risk' information as that term is interpreted by the Agency in Part V(b)(2) of the Policy Statement.

Table I. n-Octanol/Water Partition Coefficients of Several Aryl Phosphates

Chemical	CAS Number	Partition Coefficient
Kronitex (R) 50	None Assigned	$(8.5 \pm 1.5) \times 10^4$
Kronitex (R) 100	None Assigned	$(1.5 \pm 0.1) \times 10^5$
Kronitex (R) 200	None Assigned	$(1.2 \pm 0.3) \times 10^5$
Trixylyl phosphate	25155-23-1	$(5.1 \pm 0.3) \times 10^5$
Tricresyl phosphate	1330-78-5	$(8.6 \pm 4.0) \times 10^5$
Kronitex (R) 200B	None Assigned	$(1.2 \pm 0.4) \times 10^5$

Kronitex (R) 50, 100, and 200 are mixtures of triphenyl phosphate and isopropylphenyl phenyl phosphates. FMC formerly manufactured Kronitex (R) 200B, which is a mixture of triphenyl phosphate and t-butylphenyl phenyl phosphates.

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

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Submission Evaluation

The n-octanol/water partition coefficients reported for these aryl phosphates indicate that they will be fat-soluble and have the potential for bioaccumulation.

In addition to the toxicity to aquatic species noted by the submitter, aryl phosphates are known to be toxic to mammals, including humans. Partly due to their lipid solubility, these esters can be absorbed via all routes of exposure and certain of the aryl phosphates can, in sufficient amounts, produce a delayed neurotoxicity (e.g. axonal neuropathy).

Current Production and Use

A review of the production ranges (includes importation volumes) for the subject chemicals, which are listed on the initial TSCA Inventory, has shown that the following amounts were reported as being produced/imported in 1977.

Chemical Name	CAS Number	Approximate Production/ Importation Range **/
Trixylyl phosphate	25155-23-1	2 thousand to 20 thousand lbs
Tricresyl phosphate	1330-78-5	100 thousand to 1 million lbs.
Triphenyl phosphate	115-86-6	2 million to 20 million lbs.
Phenol, isopropylated, phosphate (3:1)	68937-41-7	10 million to 50 million lbs.
Phenol, isobutylenated, phosphate (3:1)	68937-40-6	0

Organophosphate esters, specifically triaryl and trialkyl/aryl phosphate esters, are widely used in many consumer and industrial products where flame retardance or fire resistance are desirable properties or mandatory requirements. The major uses of organo-

**/This production range information does not include any production/importation data claimed as confidential by the person(s) reporting for the TSCA Inventory, nor does it include any information which would compromise Confidential Business Information. The data submitted for the TSCA Inventory, inluding production range information, are subject to the limitations contained in the Inventory Reporting Regulations (40 CFR 710).

phosphate esters are as flame retardant plasticizers in polyvinyl chloride (PVC) plastic materials and as industrial fire resistant hydraulic fluids. Because of their flame retardant use in plastics, these esters are found in numerous consumer products. The use of organophosphate esters as fire resistant hydraulic fluids has led to widespread use in industries maintaining hydraulic systems close to high temperature sources. The organophosphate esters have also been used in wood preservation and as additives to lubricants and adhesives.

Comments/Recommendations

The Test Rules Development Branch/AD, with support from the Chemical Review and Evaluation Branch/AD and the Environmental and Health Review Divisions, is currently reviewing data received by the Agency pertaining to the Interagency Testing Committee's designated category: "Aryl Phosphates." Therefore, an information copy of this status report and submission should be sent to TRDB/AD for possible consideration in the ongoing review of data on the aryl phosphates. A copy of this submission and status report should also be transmitted to OWWM.

a) The FMC Corporation should be requested to describe any company actions taken, in light of the reported data on aryl phosphates, to warn workers/customers, or to reduce or eliminate exposure to the subject chemical substances.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1 4 1980

8EHQ-1179-0318
Page 1 of 3

Approved JM

Revision
Needed

DATE: Revised (May 28, 1980)

SUBJECT: Status Report* 8EHQ-1179-0318

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division, OTE

Submission Description

The CIBA-GEIGY Corporation has provided interim results from an implantation study of strontium chromate ($SrCrO_4$; CAS No. 7789-06-2) in rats. Stainless steel mesh pellets, containing strontium chromate suspended in an equal weight of cholesterol, were surgically implanted in the left inferior bronchiolus of anesthetized rats. The submitter reports that after 1 year, 29/100 $SrCrO_4$ exposed animals had died. The submitter states that "lesions consistent with the appearance of squamous cell carcinomas were observed grossly in the left lung of 21 of the dead animals." In questioning the relevance of these reported data, the submitter raises the following points:

1) The diagnosis of squamous cell carcinomas has not yet been confirmed histologically;

2) The exposure level to the test substance has not been quantified;

3) The method of administering the substance is extraordinary; and

4) The test material submitted for the the study has not been analyzed for purity or residual substances.

In addition, the submitter states that "the carcinogenicity of strontium chromate in experimental animals has been known since 1961. The compound is currently listed in this regard in Table 2 of EPA's Support Document, Test Data Development Standards: Chronic Health Effects, Toxic Substances Control Act, Section 4; (EPA-560/11-79-001)."

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

Submission Evaluation

The interim results from this implantation study are in support of previous findings that strontium chromate is carcinogenic in experimental animals.

With regard to the points raised by the submitter concerning the relevance of the reported data:

1) The laboratory scientists conducting this implantation study in rats appear to be confident that microscopic examination will confirm their gross observations of squamous cell carcinomas.

2, 3) The "not quantified" exposure level of the strontium chromate and the method of administration being extraordinary cannot change the fact that the tested substance is carcinogenic.

4) It is hoped that the tested substance would be representative of the strontium chromate being produced.

Current Production and Use

A review of the production range (includes importation volumes) statistics for strontium chromate (CAS. No. 7789-06-2), which is listed in the initial TSCA Inventory (1977), has shown that between 123 thousand and 1.2 million pounds of this chemical were produced/imported in 1977.*/

The submitter states that strontium chromate is used as a corrosion resistant agent in industrial primer coating applications. Strontium chromate is also used in pyrotechnics and in polyvinylchloride resins to produce pastel primrose yellows.

Comments/Recommendations

The submitting company reports that the previous owner of the (submitter's) $SrCrO_4$ production facilities notified its strontium chromate customers by letter in 1976 of the "potential lung cancer hazard from prolonged excessive inhalation of chromate pigment dust." The submitting company also reports that it plans to review and revise its Material Safety Data Sheet and precautionary labelling, if necessary, to ensure that its workers and customers are aware of potential dangers.

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*/This production range information does not include any production/importation data claimed as confidential by the person(s) reporting for the TSCA Inventory, nor does ot include any information which would compromise Confidential Business Information. The data submitted for the TSCA Inventory, including production range information, are subject to the limitations contained in the Inventory Reporting Regulations (40 CFR 710).

NIOSH has developed criteria documents on both chromic acid and chromium (VI).

a) The submitter should be requested to provide a full copy of the final results from this implantation study of strontium chromate when that report becomes available.

b) A copy of this submission and status report should be transmitted to NIOSH, OSHA, NCI, and CPSC.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 26 1979

8EHQ-1179-0319
Page 1 of 2

DATE: Revised (May 28, 1980)

SUBJECT: Status Report* 8EHQ-1179-0319

FROM: Walter W. Kovalick, Jr., Director
Program Integration Division (TS-793)

TO: Joseph J. Merenda, Director
Assessment Division (TS-792)

Approved ____________

Revision Needed ____________

Submission Description: Avery Island Mine and Refinery Avery Island, Louisiana: Spill of PCBs

On October 19, 1979, three General Electric 250 KVA transformers were overturned during blasting of salt at the Avery Island Mine of International Salt Company (ISC) at the 880 foot level. Investigation disclosed that the resulting spill of PCBs (into salt in the vicinity of the blast) amounted to approximately thirteen gallons. The spill area was roped off and the tranformers were removed to the surface of the mine and are located on concrete pads at the shaft house. The presence of PCBs (trade name: Inerteen, produced by Westinghouse) has been confirmed in the fluid of all three tranformers at the following levels: twenty percent in the first two and fifteen percent in the third. The incident was reported to EPA Headquarters on November 9, 1979. EPA Region Six was notified on November 20, 1979. Several phone conversations with International Salt Company were necessary in order to gather all the details of this incident.

Submission Evaluation

Available data indicate that PCBs may cause several adverse health effects in humans, mammals, birds, and aquatic organisms at extremely low concentrations. EPA has adopted the view that "safe" or threshold levels cannot be established given the present state of scientific knowledge. The first symptoms to develop after human exposure to PCBs are skin rashes (such as chloracne) and impaired liver function, both of which manifest themselves approximately one week after exposure. Later, neurological effects occur, particularly with regard to peripheral nerves in the brain.

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

Tests conducted by International Salt Company have shown no trace of PCBs in production salt to the one-half part-per-million level; ISC plans to test to five parts-per-billion. No employees came into contact with the contaminated transformer fluid, but some testing personnel did; the fluid was immediately washed off their hands and no skin rashes have been reported. ISC shovelled the contaminated material into plastics bags and placed them on the floor of the mine; employees involved in the cleanup wore closed respirators and plastics boots. The salt floor underneath the spill, while relatively impermeable, will be chipped away down to one foot and removed. Preliminary testing of this salt by ISC has indicated a PCB level of 800 to 1000 ppm.

Comments/Recommendations

This incident appears to warrant reporting as an 8(e). Even though the spill was immediately cleaned up, any spill of PCB requires careful follow-up to ensure that no adverse health effects occur, that exposure is minimized, and that the chemical is properly disposed of. Specifically, analysis of the rate of diffusion of the transformer fluid in the salt will have to be undertaken. In addition, because continued storage of contaminated material in plastic bags is unsafe and possibly illegal, the PCB-contaminated materials should be placed in metal containers. ISC has indicated that they need assistance in disposing of the contaminated materials and in monitoring for any additional diffusing transformer fluid. The Toxic Substances staff in EPA Region VI has agreed to provide assistance as needed.

TCDD analyses will have to be undertaken to determine if there is any dioxin impurity in the transformer fluid. EPA Headquarters will arrange this. In addition, International Salt should hire a dermatologist, with expertise in chloracne and associated skin rashes, to examine the testing personnel who came in contact with the fluid.

EPA Headquarters will contact FDA headquarters, and EPA Region VI will contact FDA's appropriate Regional Office, since the spill occurred near the salt (table) production area.

In summary, EPA Headquarters and EPA Region VI will follow up on this incident as needed and maintain a complete record.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

I 4 1980

8EHQ-1179-0320
Page 1 of 3

Approved ______

Revision
Needed ______

DATE: Revised (May 28, 1980)

SUBJECT: Status Report* 8EHQ-1179-0320

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division, OTE

Submission Description

The Sherex Chemical Company, Inc. reports that certain of its ethoxylated products have been found to contain significant amounts of 1,4-dioxane (CAS No. 123-91-1) as determined by gas-liquid chromotography (see Table 1 below). The submitter states that:

> Since 1,4-dioxane has been reported in an NCI study to be carcinogenic when administered to rats via drinking water, we are reporting our findings under the provisions of TSCA. Although the analysis must be confirmed by mass spec., the probability of the presence of 1,4-dioxane is sufficiently high to merit this notification.

The submitter expresses concern about the potential risks to workers involved in the production and handling of the undiluted ethoxylated materials containing 1,4-dioxane where there is the possibility of dermal and inhalation exposure. The submitter reports that these ethoxylated materials are used in the formulation of detergents, shampoos, and textile auxiliaries. It is the submitter's belief, that the concentrations of 1,4-dioxane present in the final formulated products are "at such a low level as not to pose a substantial risk. "Quantitative support for this statement, however, was not presented.

TABLE 1 - Concentrations of 1,4-Dioxane in Various Ethoxylated Products

PRODUCT	RANGE (PPM)*
ethoxylated fatty amines, (standard processing)	<10 to 450
ethoxylated fatty amines (special processing)	3400 to 6800
quanternaries from ethoxylated fatty amines	<10 to 1000
ethoxylated monoglycerides	40 to 1300
ethoxylated alcohol, phosphate ester	290
ethoxylated amide	830

(*10 ppm lower detection limit)

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

Submission Evaluation

Like many polyethylene glycols, 1,4-dioxane (an anhydride of diethylene glycol) can produce toxic effects in the kidney and liver (in humans). A characteristic nephrosis of the kidney tubules (hydropic degeneration) with associated liver cell necrosis can occur regardless of the route of 1,4-dioxane exposure (inhalation, oral ingestion, and/or skin application). Because of this, there is definite concern about human exposure to any product or material containing significant amounts of 1,4-dioxane.

The submitter should be asked to quantitate the amounts of 1,4-dioxane expected in the final formulated products and also to provide the basis for any quantification; i.e., is it based on a knowledge of the dilution rate (or some other factor) characteristically employed in the formulation of final products, or has actual quantitative chemical analysis been undertaken? In any case, the submitter should be requested to provide a "worst case" estimate of the amount of 1,4-dioxane present in final products.

Current Production and Use

The 1,4-dioxane-contaminated compounds (listed in Table 1) which are reportedly used in the formulation of shampoos, detergents, textile auxilaries, and similar products, are not described in sufficient detail to permit a review of their TSCA Inventory production ranges. The submitter should be requested to provide CAS numbers for the ethoxylated compounds. A description of the process(es), particularly the "ethoxylation step", used in the manufacture of these compounds, as well as a description of "standard" versus "special" processing should also be requested.

A review of the production range (includes importation volumes) statistics for 1,4-dioxane (CAS. No. 123-91-1) which is listed in the initial TSCA Inventory has shown that between 2 million and 15 million pounds of this chemical were produced/imported in 1977.**/

**/This production range information does not include any production/importation data claimed as confidential by the person(s) reporting for the TSCA Inventory, nor does it include any information which would compromise Confidential Business Information. The data submitted for the TSCA Inventory, including production range information, are subject to the limitations contained in the Inventory Reporting Regulations (40 CFR 710).

Comments/Recommendations

The submitting company reports that its customers and employees are being notified of the finding of significant amounts of 1,4-dioxane in its ethoxylated products.

In 1974, OSHA set the current occupational standard for 1,4-dioxane exposure at an 8 hr. time-weighted average (TWA) of 100 ppm in air (39 CFR 23540). An evaluation of the carcinogenic risk of 1,4-dioxane to man has been prepared by the International Agency for Research on Cancer (IARC Monograph, Vol. 11, 1976). In 1977, NIOSH recommended that the occupational exposure to 1,4-dioxane be controlled so that workers are not exposed at airborne concentrations greater than 1 ppm (3.6 mg/cu m) based on a 30-minute sampling period (DHEW (NIOSH) Publication No. 77-226).

Based on the results of its bioassay of 1,4-dioxane for possible carcinogenicity, the National Cancer Institute (1978) has concluded that:

> "Under the conditions of this bioassay, 1,4-dioxane induced hepatocellular adenomas in female Osborne-Mendel rats. 1,4-Dioxane was carcinogenic in both sexes of rats, producing squamous-cell carcinomas of the nasal turbinates, and in both sexes of B6C3F1 mice, producing hepatocellular carcinomas." (DHEW (NIH) Publication No. 78-1330)

A Chemical Hazard Information Profile (CHIP) on 1,4-dioxane is now in preparation.

a) The submitter should be requested to quantitate the amounts of 1,4-dioxane expected in the final formulated products and also to provide the basis for any quantitation.

b) The submitter should also be requested to provide CAS numbers for the compounds identified in Table 1 of the submission and to describe the processes used in the manufacture of these compounds.

c) A copy of this submission and status report should be transmitted to CPSC, NIOSH, OSHA, FDA, and OWWM.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 6 1980

DATE: Revised (May 28, 1980)

SUBJECT: Status Report* 8EHQ-1179-0321

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division, OTE

Approved ____

Revision
Needed ____

Submission Description

The Toms River Chemical Corporation has submitted the summarized final results from a number of in vitro and in vivo mutagenicity assays of Color Index Disperse Blue 7 Dye (CAS No. 3179-90-6). The submitter reports that although the results from several in vitro tests indicate that this material can induce point mutations, the results from in vivo testing indicate that it does not produce chromosomal aberrations.

The submitting company reports that it had previously notified the Agency (July, 1977) that in vitro Ames and mouse lymphoma test results had been obtained which supported the conclusion that one or more of the specific components of Color Index Disperse Blue 7 was a possible mutagen. At that time the company stated that additional testing was to be conducted and significant results reported to the Agency. Those additional test results are the subject of the present section 8(e) submission.

Submission Evaluation

As presented, the final results from several of the in vitro tests do indicate a mutagenic potential for C.I. Disperse Blue 7 Dye. However, without complete copies of the test protocols and data from all of the studies cited in this submission, a full evaluation of the mutagenic potential of this dye is not possible at this time.

Current Production and Use

A review of the production range (includes importation volumes) statistics for C.I. Disperse Blue 7 (Cas. No. 3179-90-6), which is listed in the initial TSCA Inventory, has shown that no 1977 production/importation was reported or that all of the production range data reported were claimed as confidential by the manufacturer(s) and importer(s) and cannot be disclosed. (Section 14(a) of the TSCA, U.S.C. 2613 (a)).**/

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

C.I. Disperse Blue 7 is used mostly in printing processes and the dying of synthetic fibers, wool sheepskins, and furs. It also has uses in the surface dying of thermoplastics.

Comments/Recommendation

The submitting company reports that its customers have been notified of this new toxicological information. In addition, the submitter reports that the warning label, developed in response to the mutagenic findings reported in 1977, will continue to be affixed to all containers of Disperse Blue 7.

a) The submitting company should be requested to provide complete copies of the final results, including test protocols and data, from the studies cited in its submission.

b) A copy of this submission and status report should be transmitted to OSHA, NIOSH, CPSC, NCI, and OWWM.

c) CHIB will review the additional information requested, revise this Status Report as appropriate, and recommend further followup assessment if warranted.

**/The data submitted for the TSCA Inventory including production range information, are subject to the limitations contained in the Inventory Reporting Regulations (40 CFR 710).

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 1 1980

DATE: Revised (May 29, 1980)

8EHQ-1279-0322
Page 1 of 2

SUBJECT: Status Report* 8EHQ-1279-0322

Approved _____

Revision Needed _____

FROM: Walter W. Kovalick, Jr., Director
Program Integration Division (TS-793)

TO: Joseph J. Merenda, Director
Assessment Division (TS-792)

Submission Description: The Clorox Company Plant, Oakland, California: accidental release of chlorine gas

On November 16, 1979, at 7:00 a.m., an accidental release of chlorine gas occurred at the Oakland plant of the Clorox Company. The cause of this release was equipment failure in piping which connected a tank car containing the gas to permanent plant facilities.

Submission Evaluation

Chlorine gas is a serious irritant. Inhalation may cause bronchitis, bronchopneumonia, tachycardia, and pulmonary edema. Chlorine gas is also an eye irritant and a mucous membrane irritant. These effects manifest themselves within forty-eight hours after exposure.

Comments/Recommendations

This incident does not appear to warrant reporting as an 8(e). Fourteen Clorox employees were taken to either the Oakland hospital or the California Industrial Medical Clinic for examination and treatment. Two employees were retained in the hospital - one for three days and the other for five days. The diagnosis was lung irritation and the prognosis was full recovery with no complications. Thirty-five people from areas surrounding the release site were examined at various hospitals and were subsequently released.

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

EPA FORM 1320-6 (REV. 3-76)

An investigation has been initiated by appropriate personnel at the Oakland plant to analyze the actions taken and to make recommendations for improvements. Clorox expects these recommendations to be implemented.

The letter and accompanying report submitted by Clorox were lacking in the detail necessary for a thorough review of the incident. There was no estimate of the amount of chemical release, duration of release and exposure periods, no specific medical examination report, and no indication of historical use. However, this information is being forwarded to EPA by Clorox, and should not significantly affect the status of the incident.

The release was investigated by EPA Region IX, California OSHA, and local fire and police departments. Following an investigation, California OSHA informed Clorox that there were no violations and that it does not intend to issue a citation.

EPA Headquarters and Region IX will follow up on this incident and will maintain a complete record.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

8EHQ-1279-0323
Page 1 of 2

DATE:

SUBJECT: Status Report* 8EHQ-1279-0323

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division/OTE

Approved JM 4/5/80

Revision Needed

Submission Description

The Atlantic Richfield Company has provided a complete copy of the final results from a number of *in vitro* and *in vivo* mutagenicity studies of Jet Fuel A, which is a complex petroleum mixture. The submitter reports that this fuel did not exhibit a positive response in the Ames test either with or without metabolic activation. However, Jet Fuel A was found to induce mutations in the *in vitro* mouse lymphoma assay (in the presence of metabolic activation), and found to produce bone marrow cell mutations in an *in vivo* cytogenetic study.

In reporting these mutagenicity data under Section 8(e) the submitting company states that it does "not interpret these findings as an indication of significant human health risk. Mutagenicity test methods only recently have been developed and therefore lack the history to verify their reproducibility. In addition, the meaning of mutagenic test results is subject to serious scientific questions."

Submission Evaluation

No increase in the incidence of mutation was observed with Jet Fuel A in the Ames *Salmonella* test in the presence or absence of the S-9 metabolic activation system. However, Jet Fuel A did induce a dose dependent increase in mutation frequency in the mouse lymphoma L5178Y assay in the presence of S-9 activation. Similarly, Jet Fuel A (via inhalation) induced significant increases in chromosomal aberrations in the bone marrow cells of rats.

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

Current Production and Use

The submitter reports that Jet Fuel A is a complex petroleum product which is sold to airline companies for use as jet airplane fuel. Although there is no one CAS number used to identify the possible available mixtures and treatment processes for this product, the submitter did provide the results of a mass spectrometry analysis. Jet Fuel A, as such, is not listed in the initial TSCA Inventory.

Comments/Recommendations

Contrary to the company's comment with regard to the significance of mutagenic test results, the Agency believes that mutagenicity test systems provide valuable data that can aid in assessing possible risks of injury to health and/or the environment posed by chemicals.

Status reports have been prepared for a number of section 8(e) submissions received on synthetic and petroleum fuels: 8EHQ-0029, 0030, 0044, 0082, 0083, 0117, 0148, 0212, 0215, 0216, 0217, 0238, 0240, 0247, 0252, 0253, 0297, 0301, 0306, and 0316. (These numbers represent the last four digits of the Document Control Officer assigned numbers.)

The National Cancer Institute/NIH is currently studying the chronic toxicity (skin-painting with mice and oral gavage with rats) of Navy Fuel JP-5, which is also a kerosene-based jet fuel.

a) The submitting company should be requested to describe any actions taken, in light of this toxicity information, to reduce or eliminate exposure to Jet Fuel A and/or to warn workers and purchasers of this submitted toxicity information.

b) Copies of this submission and status report should be transmitted to DOE, OSHA, OWWM, and ORD.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

8EHQ-0180-0324
Page 1 of 3

DATE: APR 30 [illegible]

SUBJECT: Status Report* 8EHQ-0180-0324

Approved JJM 5/2/80

Revision Needed ______

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division/OTE

Submission Description

The Diamond Shamrock Corporation (in a submission sent directly to the EPA Administrator) has reported that due to an industrial accident in its methylene chloride and chloroform production facility in Belle, West Virginia, two employees were exposed to an airborne mixture of chemicals which may have included bis-(chloromethyl)ether (BCME; CAS No. 542-88-1). The submitting company states that BCME is not normally present in its processes. Diamond Shamrock reports that since restarting the production processes, BCME has not been detected. The company states that it will continue its analytical investigation of this situation and will conduct continuing medical examinations of all known or potentially exposed individuals.

Submission Evaluation

The workers have apparently recovered from the acute exposure to the chemical mixture as none had developed any pulmonary signs or symptoms. The planned continuing medical examinations appear to be appropriate as both the irritating and carcinogenic properties of BCME are well known.

It would be of interest to know the levels of BCME detected and the sensitivity of the analytical methods used in that detection.

Current Production and Use

A review of the production ranges (includes importation volumes) for the subject chemical(s), listed on the initial TSCA Inventory, has shown that the following amounts were reported as being produced/imported in 1977:

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

Chemical Name	CAS Number	Approximate Production/ Importation Range **/
Methylene chloride	75-09-2	350 million to 1.4 billion lbs.
Chloroform	67-66-3	93 million to 350 million lbs.
Bis(chloromethyl)-ether	542-88-1	100 thousand to 1 million lbs.

Methylene chloride has uses in paint removers; propellants for aerosol sprays; blowing agents in foam; plastics processing; and solvent degreasing and extraction procedures.

Chloroform has uses as a solvent; fumigant; insecticide; fluorocarbon refrigerant and propellant; and is used in certain fluorocarbon plastic processes.

Bis(chloromethyl)ether is used as a laboratory reagent and as an intermediate for ion-exchange resins.

Comments/Recommendations

Diamond Shamrock reports that annual medical examinations are provided for its employees and that a computer tracking and surveillance system (COHESS) is maintained which provides a rapid assessment of medical status. In addition, the submitter states that any newly developed information which may inpact on the reported situation will be provided to the EPA.

In this particular case, the Diamond Shamrock Corporation's submission of section 8(e) information to the EPA Administrator's office did not unduly burden the Agency's processing of the notice. However, it should be brought to the submitter's attention that the substantial risk information reporting requirements (Part IX of the March 16, 1978, "Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" (43 FR 11110)) clearly specify that TSCA section 8(e) notices are to be sent to the Document Control Officer, Chemical Information Division, Office of Pesticides and Toxic Substances (WH-557), Environmental Protection Agency, 401 M Street S.W., Washington, D.C. 20460. A copy of the March 16, 1978, policy statement should be sent to the submitter.

**/This production range information does not include any production/importation data claimed as confidential by the person(s) reporting for the TSCA Inventory, nor does it include any information which would compromise Confidential Business Information. The data submitted for the TSCA Inventory, including production range information, are subject to the limitations contained in the Inventory Reporting Regulations (40 CFR 710).

An evaluation of the carcinogenic risk of bis(chloromethyl)ether to man has been prepared by the International Agency for Research on Cancer (IARC Monograph; Vol. 4, 1974).

NIOSH has prepared criteria documents on both chloroform (1974) and methylene chloride (1976).

The Test Rules Development Branch/AD, in conjunction with the Environmental and Health Review Divisions, is currently reviewing data received by the Agency pertaining to the Interagency Testing Committee designated chemical: "Methylene Chloride." The Chemical Review and Evaluation Branch/AD is presently developing the Phase I Assessment on Chloroform.

a) Diamond Shamrock should be requested to provide information on the levels of BCME detected at the time of the upset situation and the sensitivity of the analytical method(s) used in that detection.

b) The Agency should transmit a copy of this submission and status report to NIOSH, OSHA, CREB/AD, and TRDB/AD; the Industry Assistance Office (IAO/OPII) should consider sending this information to the producers of methylene chloride and chloroform.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 12 1980

DATE: Revised (May 28, 1980)

SUBJECT: Status Report* 8EHQ-1279-0325

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division, OTE

8EHQ-1279-0325
Page 1 of 4

Approved ____________

Revision
Needed ____________

Submission Description:

The American Cyanamid Company has provided a summary of the final results from two short-term (30 day) feeding studies of the symmetrical form of trithiocyanuric acid (TTCA; 1,3,5-triazine-2,4,6-(1H, 3H, 5H)-trithione; CAS No. 638-16-4) at concentrations of 625, 2500, and 5000 ppm in the diet of rats. The submitter reports that during the first study (performed June-July 1977), the rats at the two highest dose levels developed discoloration and eventual necrosis of the distal one-third of the tail and discoloration of the external ear. Although none of the animals at the highest dose survived to the 30th day, the lowest dose group showed no apparent effects. The second feeding study (performed April-May 1978), which reportedly confirmed the observations of the first study, included a microscopic examination of the tails and ears. The pathological findings are reported to include vascular congestion, edema, and necrosis in the tail; the ear tip was found to have a moderate infiltrate of scavenging white cells and localized necrosis.

The submitting company states that it did not report these toxicological findings to the Agency at the time (1977, 1978) "because the substance was, and has been, only in test marketing (less than 1000 lb has been manufactured to date) and we consider the possibility of any injury to health under those conditions to be negligible."

In reporting these toxicological findings under section 8(e) at this time, the submitting company states that it intends to increase TTCA production/distribution to 100,000 lb/year. However, the submitter reports that this increase will not take place until a more safe, dust-free form of TTCA can be developed. It is the submitter's judgement that the "commercial introduction of the substance does not create conditions under which one could conclude reasonably that it presents a substantial risk of injury to health."

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

Submission Evaluation

By the oral route, this symmetrical isomer of TTCA is absorbed and apparently acts on the peripheral arteries to ultimately cause congestion and stasis (stoppage) of the blood in the distal terminal vasculature, possibly resulting in gangrene.

Inhalation of dusts of this chemical may lead to similar effects on the blood vessels of the nasal passages and lungs. These effects could be caused by simple local action without necessitating systemic absorption of the chemical.

Current Production and use

A review of the production range (includes importation volumes) statistics for both tautomeric forms of trithiocyanuric acid (CAS. No. 638-16-4) which are listed in the initial TSCA Inventory (1977) has shown that between 0 and 1500 pounds of these chemicals were produced/imported in 1977.**/

The submitter anticipates the commercial use of TTCA to be as a curative agent in acrylic rubber, in which it would be incorporated at a concentration of less than one percent. It is the submitter's belief that the chemical will lose its identity by becoming part of the polymeric structure of the rubber. It is not clear that chemical analysis of the final product provides the basis for this belief; quantitative support was not presented in the submission.

Comments/Recommendations

Following a review of the provided information on TTCA, it is the Agency's preliminary determination that the submitter should have, at an earlier date, immediately informed the EPA of these toxicological findings under Section 8(e) of TSCA. The basis for this determination is as follows:

> According to Section 8(e) of the Toxic Substances Control Act (TSCA) (90 Stat. 2029, 15 U.S.C. 2607), a person who obtains substantial risk information "must immediately inform the Administrator...." The preface to Part V of the March 16, 1978, "Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" (43 FR 11110) states that a substantial risk of injury to health or the environment is a risk of considerable concern because of (a) the seriousness of the effect... and (b) the fact or probability of its occurrence." With regard to the seriousness of the effect, Part V further explains that the Agency considers the health effects for which substantial risk information must be reported to include "any pattern of effects or evidence which reasonably supports the conclusion that the chemical substance or mixture can produce....

toxic effects resulting in death, or serious or prolonged incapacitation." The information respecting these effects can be obtained directly or inferred from designed studies (e.g. in vivo experiments and tests as described in Part VI of the policy statement). With regard to the "fact or probability of its occurrence" criterion, Part V also provides that certain health effects are so serious that relatively little weight should be given to a chemical's exposure in determining whether a risk is substantial. The mere fact that an implicated chemical is in commerce constitutes sufficient evidence of exposure. In addition, Part I of the policy statement clearly specifies that the reporting requirements for TSCA Section 8(e) include test market chemicals in the definition of the manufacturing or processing of chemical substances or mixtures for commercial purposes.

Therefore, because the pattern and nature of the observed in vivo toxicological effects could produce gangrene, which is a serious and prolonged incapacitation, and the fact that TTCA was in test marketing and therefore in commerce, the Agency believes that the submitting company should have provided this substantial risk information to the EPA at an earlier date under Section 8(e) of TSCA.

The following Agency comments concern the submitter's statement that commercial introduction of TTCA "does not create conditions under which one could conclude reasonably that it presents a substantial risk of injury to health." Section 8(e) of TSCA clearly states that the information required for reporting is any information which reasonably supports a conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment. The Agency considers that reasonable support of a conclusion of substantial risk is not identical to the conclusion itself. The former typically occurs, and must be reported at an earlier stage. In addition, Part VI of the Section 8(e) policy statement specifies that a "person is not to delay reporting until he obtains conclusive information that a substantial risk exists, but is to immediately report any evidence which 'reasonably supports' that conclusive. Such evidence will generally not be conclusive as to the substantiality of the risk...."

a) The submitting company should be requested to provide complete copies of the final results, including test protocols and all data (including pathology reports) obtained from the cited feeding studies of TTCA in rats. In addition, the submitter should be requested to provide quantitative information concerning the actual amounts of TTCA ingested during these feeding studies. The submitter should also be requested to provide available chemical data with regard to residual TTCA in final products.

b) The submitting company should also be requested to describe any additional studies it has performed and/or planned for further defining the toxicity of TTCA. The Agency would be particularly interested in the results from any inhalation toxicity studies.

c) The submitting company should be requested to describe the actions it has taken, in light of this submitted toxicity information, to reduce or eliminate exposure to TTCA and to warn workers and purchasers of this reported toxicity information.

d) CHIB will review the additional information requested, revise this status report as appropriate, and recommend further followup assessment if warranted.

e) A copy of this submission and status report should be transmitted to OSHA, NIOSH, FDA and CPSC.

**/This production range information does not include any production/importation data claimed as confidential by the person(s) reporting for the TSCA Inventory, nor does it include any information which would compromise Confidential Business Information. The data submitted for the TSCA Inventory, including production range information, are subject to the limitations contained in the Inventory Reporting Regulations (40 CFR 710).

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

8EHQ-0979-0326S
8EHQ-0180-0326 Suppl. A
Page 1 of 4

DATE: [illegible]

SUBJECT: Status Report* 8EHQ-0979-0326S
8EHQ-0180-0326 Supplement A

Approved 4/10/80

Revision Needed ______

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division, OTE

Submission Description

In its initial submission (8EHQ-0979-0326S), the Shell Oil Company reported that two specific products, the sodium and ammonium salts of alcohol ethoxysulfates, were found to contain between 130 and 2500 ppm of 1,4-dioxane (CAS No. 123-91-1). The submitter also stated that 1,4-dioxane forms during the conversion of alcohol ethoxylate to the alcohol ethoxysulfate salts. Although supporting quantitative evidence was not provided, the submitter reported that dioxane is not present in the starting alcohol ethoxylated materials.

In providing the initial information under Section 8(e), the submitter stated that "1,4-dioxane was shown in an NCI study to be carcinogenic when given to rats at 5,000 and 10,000 ppm in drinking water" and expressed concern about the potential risks posed to the health of workers involved with the sulfation process, and the further product handling, where there is the possibility of dermal and/or inhalation exposure. The submitter also reported that the alcohol ethoxysulfate salts are used in the formulation of detergents, shampoos, and similar products requiring high foaming and surface-active properties.

In the supplemental submission (8EHQ-0180-0326 Supplement A), Shell reports that as soon as it became aware of the potential risks involved with the handling of 1,4-dioxane-containing materials, monitoring activities were initiated for the personnel and work area in the sulfation step, several product streams, and the contents of several tanks and tank trucks. The submitter states that the analytical results (provided in the supplement) show that the atmospheric levels for 1,4-dioxane were no more than 0.1 ppm for an 8-hour time-weighted average (TWA) which, as the submitter points out, is below the current OSHA standard of

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

100 ppm (TWA) and the ACGIH TLV of 50 ppm. However, the submitter does report that the concentrations of 1,4-dioxane in liquid ethoxysulfate were found to vary between 220 and 3,160 ppm.

Based on this recently developed exposure information the submitter states that "we are now of the opinion that the presence of 1,4-dioxane does not constitute a substantial risk situation to people involved in the sulfation process or in the formulation process, particularly if our suggested safe handling procedures are followed." The submitter further states that "it is our confirmed belief that after formulation, concentrations of the dioxane are lowered sufficiently that the final products do not pose a substantial risk for those who are exposed to them." The quantitative support for this statement, however, was not provided by the company in either the initial or supplemental submissions.

Submission Evaluation

Like many polyethylene glycols, 1,4-dioxane (an anhydride of diethylene glycol) can produce toxic effects in the kidney and liver (in humans). A characteristic nephrosis of the kidney tubules (hydropic degeneration) with associated liver cell necrosis can occur regardless of the route of 1,4-dioxane exposure (inhalation, oral ingestion, and/or skin application). Because of this, there is definite concern about human exposure to any product or material containing significant amounts of 1,4-dioxane.

As reported, the inhalation exposure to 1,4-dioxane does appear to be negligible (i.e. 1 ppm). However, the 3000 ppm dioxane detected in several of the liquid materials does indicate a significant dermal exposure which can lead to serious health effects in unprotected/uninformed workers.

The submitter should be asked to quantitate the amounts of 1,4-dioxane expected in the final formulated products and also to provide the basis for any quantification; i.e., is it based on a knowledge of the dilution rate (or some other factor) characteristically employed in the formulation of final products, or has actual quantitative chemical analysis been undertaken? In any case, the submitter should be requested to provide a "worst case" estimate of the amount of 1,4-dioxane present in final products.

Current Production and Use

Neither the starting alcohol ethoxylated material nor the 1,4-dioxane-contaminated compounds (which are reported by the submitter to be used in the formulation of shampoos, detergents, and similar products) are described in sufficient detail in these submissions to permit a review of their TSCA Inventory production ranges.

A review of the production range (includes importation volumes) statistics for 1,4-dioxane (CAS. No. 123-91-1) which is listed in the initial TSCA Inventory has shown that between 2 million and 15 million pounds of this chemical were produced/imported in 1977.**/

Comments/Recommendations

The submitting company reports that its customers, its two toll producers, and OSHA have been notified that 1,4-dioxane has been detected in these alcohol ethoxysulfate products.

In 1974, OSHA set the current occupational standard for 1,4-dioxane exposure at an 8 hr. time-weighted average (TWA) of 100 ppm in air (39 CFR 23540). An evaluation of the carcinogenic risk of 1,4-dioxane to man has been prepared by the International Agency for Research on Cancer (IARC Monograph, Vol. 11, 1976). In 1977, NIOSH recommended that the occupational exposure to 1,4-dioxane be controlled so that workers are not exposed at airborne concentrations greater than 1 ppm (3.6 mg/cu m) based on a 30-minute sampling period (DHEW (NIOSH) Publication No. 77-226).

Based on the results of its bioassay of 1,4-dioxane for possible carcinogenicity, the National Cancer Institute (1978) has concluded that:

> "Under the conditions of this bioassay, 1,4-dioxane induced hepatocellular adenomas in female Osborne-Mendel rats. 1,4-Dioxane was carcinogenic in both sexes of rats, producing squamous-cell carcinomas of the nasal turbinates, and in both sexes of B6C3F1 mice, producing hepatocellular carcinomas." (DHEW (NIH) Publication No. 78-1330)

The Agency has recently received two additional 8(e) submissions (8EHQ-1179-0320 and 8EHQ-0280-0331) which also reported the detection of 1,4-dioxane in other ethoxylated products.

A Chemical Hazard Information Profile (CHIP) on 1,4-dioxane has been prepared by the Chemical Hazard Identification Branch/AD. The Chemical Review and Evaluation Branch/AD is now preparing an in-depth source and health effects assessment (Phase I) for 1,4-dioxane.

a) The submitting company should be requested to provide the data which were the basis for its statement that no dioxane is present in the starting alcohol ethoxylated materials. In addition, the submitter should be requested to quantitate the amounts of 1,4-dioxane expected in the final formulated products and also to provide the basis for any quantitation.

b) The submitting company should also be requested to provide any available data on the actual chemical compositions (including amounts and CAS numbers of components where available) of the starting alcohol ethoxylated materials and the alcohol ethoxysulfate salt compounds identified in its submission. In addition, the submitter should be requested to provide, if available, any additional information on the processes by which 1,4-dioxane is formed during the conversion of the alcohol ethoxylates to the alcohol ethoxysulfate salts.

c) Copies of these submissions and the status report should be transmitted to CPSC, NIOSH, OSHA, FDA, OWWM, and CREB/AD.

**/This production range information does not include any production/importation data claimed as confidential by the person(s) reporting for the TSCA Inventory, nor does it include any information which would compromise Confidential Business Information. The data submitted for the TSCA Inventory, including production range information, are subject to the limitations contained in the Inventory Reporting Regulations (40 CFR 710).

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

8EHQ-0180-0327
Page 1 of 2

DATE: APR 15 1980

SUBJECT: Status Report* 8EHQ-0180-0327

Approved JM 4/14/80

Revision Needed ____________

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph Merenda, Director
Assessment Division, OTE

Submission Description

The Atlantic Richfield Company reports that preliminary results from a planned 80-week skin-painting study show that each of two tested materials (ARCO LB-7979 and Provalent 4A) had produced skin tumors when applied twice weekly to the shaven skin of mice. The submitter states that all tumors observed thus far have been characterized as benign by the performing laboratory. The incidence of tumors in each test group (50 mice) is presented in Table I below.

Atlantic Richfield states that it had initiated this study of ARCO LB-7979 and Provalent 4A in response to an earlier section 8(e) submission from the Standard Oil Company (Indiana) (8EHQ-0579-0283). In that submission Standard Oil reported that one of its developmental products (Wellaid PG-100) had been shown to be carcinogenic in a mouse skin-painting study. The ARCO LB-7979 product is a chemical component of Wellaid PG-100 and Provalent 4A is purchased by Atlantic Richfield from the Mobil Oil Corporation for use in the formulation of ARCO LB-7979.

Table I. Tumor Incidence (1/Animal) at 17 Weeks

Chemical Name	No. of Tumors	Percentage	Average Latent Period - Weeks
ARCO LB-7979	2	4	14.0
Provalent 4A	16	32	15.8
Benzo(a)pyrene (positive control)	3	6	10.0

Atlantic Richfield states that the incidence of apparently benign skin tumors observed at this stage of this study does not indicate a substantial health risk to humans. The submitter also states that subsequent results will be provided periodically to the EPA.

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

Submission Evaluation

Both ARCO LB-7979 and Provalent 4A have produced benign skin tumors in mice at approximately 16 weeks. In this respect, these preliminary results are similar to those previously reported for Wellaid PG-100 (8EHQ-0579-0283). Wellaid PG-100 was shown to produce benign skin papillomas at the application site at about 16 weeks. In addition, Wellaid PG-100 produced malignant skin tumors after the 26th week. Although the results from the 26th week of the current study of ARCO LB-7979 and Provalent 4A are not yet available for determining their possible carcinogenicity, the oncogenic capability of both products has been established.

Current Production and Use

Neither the ARCO LB-7979 product nor the Provalent 4A product are described in sufficient detail to permit a review of TSCA Inventory production ranges. CAS numbers should be requested for all chemical components of these products.

According to the submitter, the purchased Provalent 4A is used in the formulation of ARCO LB-7979 and other specialty chemicals for industrial applications. To the submitter's knowledge, none of these specialty chemicals are used in consumer products.

Comments/Recommendations

The Atlantic Richfield Company reports that their employees, their customers, and the supplier of Provalent 4A (Mobil Oil Corporation) are being notified of these interim test results and of precautionary measures to be taken in handling products containing Provalent 4A.

a) The Atlantic Richfield Company should be requested to provide the CAS numbers of the chemical components of the ARCO LB-7979 product. The Mobil Oil Corporation should be requested to provide the CAS numbers of the components in its Provalent 4A product.

b) The Agency should transmit a copy of this submission and status report to the Mobil Oil Corporation, the Standard Oil Company (Indiana), NIOSH, OSHA, DOE, DOT, and OWWM.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

8EHQ-0180-0328S
Page 1 of 3

DATE: APR 22 1980

SUBJECT: Status Report* 8EHQ-0180-0328S

Approved JM 5/2/80

Revision Needed

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division

Submission Description

The CIBA-GEIGY Corporation has reported that gross observations made after the 24th month of a lifetime mouse skin-painting study indicate that an imported developmental "dimethylhydantoin - derived epoxy resin" (XB-2793) had produced skin "tumors" at the site of application. The histopathological examination of the test animals is reported to be underway at the performing laboratory in Switzerland. The submitting company also provided a summary of mutagenicity data from several in vitro tests of XB-2793 and another product (XB-2826), each with and without metabolic activation. The exact chemical identities of the XB-2793 and the XB-2826 products have been claimed as confidential by the submitting company. In its submission to the EPA, the company states:

> "Although we are reporting the preliminary dermal carcinogenicity assay information under TSCA Section 8(e), no conclusion has been made as to whether this information or the mutagenicity test results constitute a substantial risk since:
>
> 1. The dermal carcinogenicity study is incomplete and final results are not yet available.
> 2. The description of the initial gross observations indicates the lesions are limited to the site of application. Histopathology of all tissues and suspected lesions are now underway.
> 3. The in vitro mutagenicity results are inconclusive since inconsistencies exist between batches and test systems."

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CIBA-GEIGY also reports that a more complete summary of the preliminary data from the skin-painting study of XB-2793 is now in preparation and, in addition, a final report is to be prepared after completion and evaluation of the histopathology. The submitter states that copies of each report will be forwarded to the EPA.

Submission Evaluation

The diaryl, the monoaryl-monoalkyl, and the dialkyl substituted hydantoins have been associated with a variety of serious toxicities including lymph adenopathy (which resembles Hodgekin's Disease) and malignant lymphoma. Hydantoins have also been associated with aplastic anemia of bone marrow origin and have been reported to produce fatal hepatic necrosis and lupus erythematosus (via an effect on the adrenal cortex). Substituted hydantoins have been used extensively in medicine (e.g. diphenlylhydantoin which is used in the treatment of epilepsy). Replacing the aromatic substituents with alkyl groups can alter the central nervous system effects toward depression.

Although XB-2793 has not been demonstrated histopathologically to be carcinogenic, the summarized preliminary results provided in the submission do indicate that this product is oncogenic (i.e. produces tumors) in mice via skin-painting.

With regard to the submitter's statement that the in vitro mutagenicity results are inconsistent and inconclusive, it should be noted that while neither XB-2793 nor XB-2826 were shown to be mutagenic in the Saccharomyces Cerevisiae D4 (yeast) assays, mutagenic activities were demonstrated for both XB-2793 and XB-2826 in almost all of the performed Salmonella Typhimurium bacterial assays with and without metabolic activation. In addition, the XB-2793 product was shown to be positive (with and without activation) in an in vitro mouse lymphoma assay. (The XB-2826 was apparently not tested in this particular assay.) It should also be noted that the negative results obtained in the yeast assay may have been due to the low permeability of the yeast cell wall for certain types of chemical molecules.

Current Production and Use

Because the chemical identities of XB-2793 and XB-2826 have been held as confidential by the submitter, a full report of the non-confidential production/importation range information from the initial TSCA Inventory (1977) will not appear in this status report. **/ However, the submitter does report non-confidentially that the combined annual volume of XB-2793 and XB-2826 imported by the CIBA-GEIGY Corporation falls within the inventory production range 2 (10,000 to 100,000 pounds).

**/The data submitted for the TSCA Inventory, including production range information, are subject to the limitations contained in the Inventory Reporting Regulations (40 CFR 710).

The submitter states that both XB-2793 and XB-2826 are sampled or sold for industrial use only and reports that there is no consumer exposure because these materials are fully reacted to inert polymeric products prior to reaching consumers. The submitter did not, however, provide any quantitative data in the submission to support this contention.

Comments/Recommendations

CIBA-GEIGY reports that it is reviewing the adequacy of the XB-2793 and XB-2826 current labelling and Material Safety Data Sheets in light of the new submitted information and will inform the Agency of any company decisions regarding these reviews and of any customer/employee notifications.

a) The submitting company should be requested to provide the analytical data which were the basis for its contention that there is no exposure to residual XB-2793 and/or XB-2826 in polymeric end-products.

b) The submitter should also be requested at this time to provide full copies of the protocols and data obtained from the mutagenicity studies cited in this submission.

c) The Chemical Hazard Identification Branch (CHIB/AD) will review the additional data requested and/or provided, revise this Status Report as appropriate, and recommend further followup assessment if warranted.

d) The Agency should transmit a copy of the non-confidential submission and status report to NIOSH, OSHA, and NCI.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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8EHQ-1279-0329
Page 1 of 1

Approved JM

Revision Needed

DATE: Revised (May 28, 1980)

SUBJECT: Status Report* 8EHQ-1279-0329

FROM: Walter W. Kovalick, Jr., Director
Program Integration Division (TS-793)

TO: Joseph Merenda, Director
Assessment Division (TS-792)

Submission Description: du Pont plant at New Johnsonville, Tennessee: accidental release of chlorine gas

On Tuesday, December 4, 1979, chlorine gas was released into the atmosphere at a loading dock of the du Pont plant at New Johnsonville, Tennessee. The release occurred when a flange split on a chlorine barge unloading line; within twelve minutes the flange was valved off.

Submission Evaluation

Chlorine gas is a serious irritant. Human exposure can result in tachycardia, bronchopneumonia, and pulmonary endema. Chlorine gas is also a serious mucous membrane and eye irritant.

Comments/Recommendations

This incident does not appear to warrant reporting as an 8(e). Du Pont estimated that the amount of chlorine released may have been about .5 to 1.5 tons. An insignificant chlorine odor was detected but no significant chlorine fumes. A du Pont investigation found no evidence of any damage to humans or the surrounding environment, and no evidence of damage to surrounding biota.

Du Pont concluded that "the pattern, extent, and amount of chlorine in this incident did not result in an 'emergency incident of environmental contamination' under section 8(e) of TSCA." This appears to be the correct decision.

EPA Region IV and Headquarters will follow-up and maintain a complete record of this incident.

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

8EHQ-0180-0330
Page 1 of 5

DATE: APR 7 1980

Approved JM 4/7/80

SUBJECT: Status Report* 8EHQ-0180-0330

Revision
Needed ____________

FROM: Frank D. Kover, Chief Justine Welch/for
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division, OTE

Submission Description

In a section 8(e) submission to the EPA's Region I Office (Boston, Massachusetts), the General Electric Company reports that it has been conducting a study of possible industrial pollution of groundwater at several locations in the vicinity of its Pittsfield (Mass.) manufacturing complex. The submitter reports that mineral oil containing PCBs (polychlorinated biphenyls) in the parts per million (ppm) range had been detected at the groundwater surface in certain areas. At one particular location (a sump in the basement of a nearby residence) an estimated gallon of oil had accumulated which was found to contain approximately 200-300 ppm PCBs. It is this circumstance which prompted the company to submit this information under TSCA section 8(e).

In addition, the company reports that [mono]chlorobenzene, at concentrations of 5 mg/l and 30 mg/l, had been detected in the water from 2 of 21 observation wells installed at depths up to 50 feet at varying distances from the manufacturing site. The submitter states that all of the wells are now being analyzed for all priority pollutants.

In addition to having notified EPA's Region I Office, General Electric also reports that this study "has been and continues under review by personnel of the Massachusetts Division of Water Pollution and the Massachusetts Department of Environmental Quality Engineering."

Submission Evaluation

PCBs are among the most stable chemicals known. Once released into the environment, they decompose very slowly over a period of several decades. Due to this stability, they remain in the environment and are taken up and accumulated in fatty tissues. This accumulation in organisms is significant because PCBs are hazardous to health at extremely low levels. Specifically, PCBs have been shown to cause chronic toxic effects in many species at less than 10 parts per million (ppm). There are well documented tests on laboratory animals which show that PCBs can cause reproductive failures, gastric disorders, skin lesions, tumors, and other effects of concern.

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

In man, PCBs can enter the body through the lungs, the gastrointestinal tract, and the skin. After absorption, PCBs are circulated in the blood throughout the body and are stored in fatty tissue and a variety of organs, including the liver, kidneys, lungs, adrenal glands, brain, heart, and skin.

Therefore, the submitter's finding of one gallon of oil containing 200-300 ppm PCB indicates an opportunity for significant exposure with a resultant health and environmental hazard.

In addition, there is concern with regard to the [mono]chlorobenzene concentrations of 5 mg and 30 mg per liter of water in the observation wells. If these concentrations of chlorobenzene have access to drinking water, long term consumption/use could possibly lead to the following human health effects: eye and skin irritation, liver and kidney damage, and possible blood disorders.

Current Production and Use

Polychlorinated biphenyls (PCBs; no designated CAS number) are members of a broad family of organic chemicals known as chlorinated hydrocarbons. Although PCBs may be produced naturally in the environment, almost all PCBs in existence today have been synthetically manufactured.

Primary uses of PCBs were, and continue to be, electrical transformer cooling liquids and capacitor dielectric fluids. Most of the PCBs marketed in the United States are still in service in these applications. However, PCBs have also been used in a variety of other applications such as heat transfer systems and hydraulic fluids; dye carriers in carbonless copy paper; plasticizers in paints, adhesives, and caulking compounds; fillers in investment casting wax; and as dust control agents, sealants, and coatings on roads.

PCBs have a heavy liquid, oil-like consistency, have high boiling points, and weigh 10-12 pounds per gallon. Other important properties include: a high degree of chemical stability, low solubility in water, high solubility in fat, low flammability, and low electrical conductivity. These physical/chemical properties have made PCBs commercially attractive.

Current EPA PCB Regulations

A report by the President's Council on Environmental Quality in May 1972, recommended that Congress enact the Toxic Substances Control Act (TSCA) to provide the regulatory authority required to deal with PCBs and other chemicals. Before the Toxic Substances Control Act, EPA could only regulate facilities that discharged PCBs into naviagable waterways. On July 23, 1976 (41 FR 30468), EPA proposed to ban the discharge of PCBs by electrical transformer and capacitor manufacturers. A final rule was promulgated under Section 307(a) of the Federal Water Pollution Control Act on February 2, 1977 (42 FR 6532).

In 1976, Congress passed the Toxic Substances Control Act. At that time there was widespread recognition and concern regarding the serious, adverse effects PCBs have on the environment and human health. Congress responded to this problem by including a special section in TSCA, Section 6(e), prohibiting future manufacturing, processing, distribution in commerce, and use of PCBs and providing for adequate marking and disposal of the PCBs still in use.

Since then, EPA has implemented the provisions under Section 6(e) of TSCA. The following is a summary of these actions:

On February 17, 1978, EPA promulgated the PCB Marking and Disposal Rule (40 CFR 761). In this rule, EPA established specific requirements for the marking and disposal of PCBs according to the nature and concentration of the PCBs in question.

On May 31, 1979, EPA promulgated the PCBs Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions (PCB Ban Rule) (40 CFR 761). Specifically, this rule:

1) Prohibits all manufacturing of PCBs after July 2, 1979, unless specifically exempted by EPA;

2) Prohibits the processing, distribution in commerce, and use of PCBs, except in a totally enclosed manner after July 2, 1979, unless specifically authorized by EPA;

3) Authorizes certain processing, distribution in commerce, and use of PCBs in a non-totally enclosed manner;

4) Prohibits all processing and distribution in commerce of PCBs after July 1, 1979, unless specifically exempted by EPA.

The regulatory scheme developed in the PCB Marking and Disposal Rule and the PCB Ban Rule was designed to minimize exposure to humans and the environment while allowing the continued use of those PCBs which are totally enclosed or have been granted authorizations or exemptions. "Totally enclosed manner" was defined by Congress in TSCA to mean a manner which will ensure no significant exposure of the human beings or the environment to PCBs, as determined by EPA by rule (Section 6(e)(2)(C)). The final ban rule provides that human or environmental exposure to any detectable quantities of PCBs shall be deemed significant.

The use of intact, non-leaking PCB transformers, PCB-contaminated tranformers, electromagnets, and PCB capacitors and equipment containing such capacitors is considered a "totally enclosed" activity. However, servicing of such equipment is not considered a totally enclosed activity.

Congress provided a mechanism to allow exceptions to the statutory ban of non-totally enclosed activities (Section 6(e)) by permitting EPA to authorize some activities which are not totally enclosed. In order to authorize an activity, EPA must find that continuation of the activity does not present an unreasonable risk of injury to human health or to the environment.

The following non-totally enclosed activities have been granted authorizations until July 1, 1984: the servicing of PCB-containing transformers; the use of PCBs in heat transfer systems; the use of PCBs in hydraulic systems; the servicing of PCB electromagnets; the use of small quantities of PCBS for research and development; and the use of PCBs as a microscopy mounting medium. The use of PCBs in natural gas pipeline compressors is authorized until May 1, 1980. Authorizations until January 1, 1982, have been granted for the use of PCBs in mining equipment, the servicing of mining equipment, and the use of PCBs in pigments. Finally, because of the significant quantities of carbonless copy paper that contains small amounts of PCBs in government, industry, and personal files, the rule authorizes continued maintenance of such paper.

Exceptions may also be made to the manufacturing ban or to the ban on PCB processing and distribution in commerce. These exceptions are referred to in TSCA as exemptions (Section 6(e)(3)(B)). Before an exemption can be granted, there must be a determination that an unreasonable risk is not present and that good faith efforts have been made to develop substitutes for the PCBs.

Although PCBs remain in use, EPA carefully considers the circumstances and conditions of each remaining use. Most of the remaining PCBs are in totally enclosed electrical equipment which will be replaced in the next few years as this equipment is serviced or retired. Most importantly, EPA has strict servicing, storage and disposal requirements to protect against escape of the PCBs into the environment. Further, authorization of each remaining use will continue to be reviewed on a regular basis to ensure that they do not present an unreasonable risk to human health and the environment.

Comments/Recommendations

In this particular case, the General Electric Company's submission of this section 8(e) information to the Region I Office did not unduly burden the EPA's processing of the notice. However, it should be brought to the submitter's attention that the substantial risk information reporting requirements (Part IX of the March 16, 1978, "Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" (43 FR 11110)) clearly specify that TSCA section 8(e) notices are to be sent to the Document Control Officer, Chemical Information Division, Office of Toxic Substances (WH-557), Environmental Protection Agency, 401 M Street S.W., Washington, D.C. 20460. A copy of the March 16, 1978, policy statement should be sent to the submitter.

Region I (EPA) has recommended that this site of groundwater contamination be placed on the list of Uncontrolled Hazardous Waste Sites.

A report (FRL-756-4) on the human effects caused by exposure to chemical contaminants in drinking water has been prepared by the National Academy of Sciences in accordance with the Safe Drinking Water Act (P.L. 93-523).

The Test Rules Development Branch/AD, in conjunction with the Environmental and Health Review Divisions, is currently reviewing data received by the Agency pertaining to the Interagency Testing Committee's designated category: "Mono- and Di-Chlorinated Benzenes."

a) The EPA Region I Office is monitoring company and state/local agency actions and will continue with necessary follow-up activities involving this reported groundwater contamination.

b) A copy of this status report should be transmitted to the EPA Region I Office (Hazardous Waste Task Group/Enforcement Division).

c) Copies of the submission and status report should be transmitted to OWWM, SAD/OPII, TRDB/AD, and PCB Team/CAD/OCC.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 25 1979

8EHQ-0779-0010
Followup Response
Page 1 of 2

DATE: Revised (May 28, 1980)

SUBJECT: Status Report* 8EHQ-0779-0010
Followup Response

Approved ______

Revision
Needed ______

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division, OTE

Submission Description

The American Petroleum Institute has submitted information relating to the physical, chemical, and compositional properties of "rubber solvent," "60 solvent," and "high aromatic solvent." Information is included on the current availability of these solvents in commerce. This additional information, sent in response to an EPA request, is supplemental to a previous submission (8EHQ-1077-0010), which reported the possible mutagenic activity of these three solvents.

Submission Evaluation

The chemical analyses show that the tested "rubber solvent" contained 1.5% benzene by volume. The concern is 4-fold:

(1) benzene can cause aplastic anemia. The bone marrow becomes incapable of producing mature red blood cells. This failure of bone marrow activity may also involve white blood cells and blood platelets.

(2) aplastic anemia may progress to leukemia.

(3) exposure to benzene increases the risk for developing lymphoid cancers.

(4) exposure to benzene increases the risk five-fold for developing all types of cancer.

The chemical analyses also show that the tested "high aromatic solvent" contained polynuclear aromatic hydrocarbons. Their presence raises the question of carcinogenicity.

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

Current Production and Use

The submitter states that the "rubber solvent" and "high aromatic solvent" petroleum products currently available in commerce ("60 solvent" appears to be no longer available commercially as such) can be variable blends of several different Petroleum Refinery Process Streams (TSCA Generic Terms) all of which are listed in the TSCA Inventory. No other information on the current production volumes or uses of the solvents was located in the secondary sources consulted.

Comment/Recommendations

Copies of the original submission (8EHQ-1077-0010), the followup submission (8EHQ-0879-0010 Followup), and their respective status reports should be transmitted to NIOSH, OSHA, OWWM, CPSC, OPP, and CRFB.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 6 1980

8EHQ-1179-0028
Supplement
Page 1 of 2

DATE: Revised (May 28, 1980)

SUBJECT: Status Reports* 8EHQ-1179-0028
Supplement

Approved JM

Revision
Needed

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division, OTE

Submission Description

This supplemental submission by the Union Carbide Corporation presents the final results from a co-sponsored mouse skin painting study designed to determine the carcinogenic potential of neopentylglycol diacrylate (NPGDA; CAS No. 2223-82-7). The report indicates that upon repeated NPGDA application (3 times per week) over the lifetime of the animals, 8/37 mice developed neoplastic skin lesions. Of those lesions, 5 squamous cell papillomas and 3 squamous cell carcinomas were confirmed by histopathology. The submission also reports that a squamous cell carcinoma (cause undetermined) of the skin had developed near the right eye of one control mouse treated with the acetone vehicle.

The original submission (8EHQ-0178-0028) which reported the preliminary results from this dermal carcinogenesis study was reviewed previously by the Agency. A status report was prepared at that time.

Submission Evaluation

The earlier suspicion, raised by the interim results (8EHQ-0178-0028), that NPGDA is a carcinogen is strongly supported by the data presented in this final report.

There is some concern, however, about the cause of the skin carcinoma observed in the acetone control group. Is there a possibility that the test animals were exposed to some other carcinogen or is this tumor type being considered "spontaneous" as observed in historical controls.

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

EPA FORM 1320-6 (REV. 3-76)

Current Production and Use

A review of the production range (includes importation volumes) statistics for neopentylglycol diacrylate (CAS. No. 2223-82-7) which is listed in the initial TSCA Inventory (1977) has shown that between 1 thousand and 8.6 thousand pounds of this chemical were produced/imported in 1977.**/

As stated in the original status report, NPGDA appears to have certain uses in UV-curable coatings, adhesives, and inks.

Comments/Recommendations

The submitting company stated in the original submission that its employees, customers, suppliers, and another producer had been notified of the preliminary results showing tumorigenic activity of NPGDA and the need for precautions against exposure.

The Agency has previously received and evaluated section 8(e) submissions on several other acrylates: ethyl acrylate (8EHQ-0978-0250); 2-ethylhexyl acrylate (8EHQ-1278-0262); glycidyl acrylate [GA] and glycidyl methacrylate [GMA] (8EHQ-0179-0270).

Chemical Hazard Information Profiles (CHIP) for ethyl acrylate, 2-ethylhexyl acrylate and NPGDA are now in preparation.

a) According to the original submission, the final results of this mouse dermal study of NPGDA will be made available to those people known to have potential exposure to this chemical. It is not clear in the cover-letter to the present submission if this action has been taken. This point should be clarified with the submitter.

b) NPGDA should be considered as a candidate for inclusion in the 8(a) use rule.

c) A copy of the original and supplemental submissions and the respective status reports should be transmitted to NIOSH,OSHA, CPSC, NCI, and TRDB.

**/This production range information does not include any production/importation data claimed as confidential by the person(s) reporting for the TSCA Inventory, nor does it include any information which would compromise Confidential Business Information. The data submitted for the TSCA Inventory, including production range information, are subject to the limitations contained in the Inventory Reporting Regulations (40 CFR 710).

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 26 1980

8EHQ-1079-0211
Followup Response
Page 1 of 3

Approved ____

Revision Needed ____

DATE: Revised (May 28, 1980)

SUBJECT: Status Report* 8EHQ-1079-0211
Follow Up Response "B"

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division, OTE

Submission Description

Per the Agency's request in a follow-up letter, the Ethyl Corporation has provided the full final results of a teratology study of methylcyclopentadienyl manganese tricarbonyl (MMT; CAS No. 12108-13-3) in rats.

The submitting company, in its initial submission on MMT (8EHQ-0778-0211) stated that it had obtained preliminary information which if found to be reliable, could reasonably support the conclusion that MMT was teratogenic in laboratory rats. However, the submitter expressed "grave reservations" about the data and indicated that further study and an audit of the information was underway. After completion of these activities, the submitter forwarded a follow-up report to the Agency.

In that follow-up report (8EHQ-1078-0211 Follow-up Response A), the submitter provided a summary of the teratology results and stated that based upon his audit, the "data does not support a conclusion that MMT is a teratogen." The submitter further concluded that, in this instance, his company "does not possess information which reasonably supports the conclusion that MMT presents a substantial risk of injury to health or the environment." The Agency in its evaluation of the information, however, concluded that the data as presented could not be used to support the contention that MMT was not a teratogen. It was therefore the Agency's preliminary determination that the toxicological information as submitted appeared to offer reasonable support for a conclusion of substantial risk.

In its follow-up to Response A the Agency requested that the submitter provide a complete copy of the final results, including test protocols and data, obtained from the teratology study. Per the Agency's request, the submitter forwarded the final report; that information (Response B) comprises the subject of this status report.

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

In Response B, the submitter also states that based on concerns about the quality and reliability of the data, the teratology study has been repeated. According to the submitter, the results obtained from the second study appear to substantiate his earlier conclusion that the "data does not support a conclusion that MMT is a teratogen." The data from this new teratology study were not, however, included in the present submission.

Submission Evaluation

The final report of the initial teratology study will not adequately support a contention that MMT is not a teratogen. The significance of 5/5 litters with an increased incidence of ocular and vertebral malformations cannot be minimized by speculation concerning the high maternal toxicity observed, the group sizes being too small for statistical analysis, or the origin of the rats used for the study. Abnormal events affecting the fetuses occurred during this study and MMT appears to have been responsible for those events.

Therefore, based on the data provided thus far by the submitter, it is strongly suspected that MMT is a potential teratogen.

Current Production and Use

A review of the production range (includes importation volumes) statistics for MMT (CAS No. 12108-13-3) which is listed in the initial TSCA Inventory (1977) has shown that no 1977 production/importation was reported or that all of the production range data reported were claimed as confidential by the manufacturer(s) and importer(s) and cannot be disclosed. [Section 14(a) of the TSCA, U.S.C. 2613 (a)].**_/

MMT is currently used in some leaded gasolines as an anti-knock agent. Provisions of the 1977 Amendments to the Clean Air Act resulted in a ban on the use of MMT in unleaded gasoline sold in the U.S. after September 15, 1978. However, on May 31, 1979, EPA suspended enforcement of the ban on MMT in unleaded gasoline until October 1, 1979. This EPA action was taken in order to increase the summer supply of unleaded gasolines and therefore decrease the need for consumers to switch to the leaded fuels which would have resulted in severe damage to pollution-control catalysts in many of the newer automobiles.

**_/The data submitted for the TSCA Inventory including production range information, are subject to the limitations contained in the Inventory Reporting Regulations (40 CFR 710).

Comments/Recommendations

a) The submitter should be requested to provide, when available, a complete copy of the final results, including test protocols and data, from the second teratology study of MMT in rats.

b) CHIB will review the additional information requested, revise this Status Report as appropriate, and recommend further follow-up assessment if warranted.

c) A copy of this submission and status report should be transmitted to OSHA, NIOSH, OAQPS, OMSAPC, and ORD.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 31 1979

8EHQ-0879-0250
Followup Response
Page 1 of 2

DATE: Revised (May 28, 1980)

SUBJECT: Status Report*8EHQ-0879-0250
Followup Response (A)

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch,

TO: Joseph J. Merenda, Director
Assessment Division

Approved ____

Revision Needed ____

Submission Description

The Celanese Corporation has submitted the final results from several interim sacrifices from a co-sponsored two-year inhalation toxicity study of ethyl acrylate (CAS No. 140-88-5) in mice and rats. These final results, including test protocols and data, were submitted in response to an EPA request for additional information which was based on its evaluation of the summarized preliminary sacrifice results presented in the original submission (8EHQ-1078-0250).

Submission Evaluation

This followup information does not significantly alter the Agency's preliminary evaluation of the summarized results presented in the original submission.

The final results from the six-month ethyl acrylate exposure to mice do indicate that the chemical is a volatile irritant capable of provoking histological changes in the nasal mucosa. The significance of the metaplasia will probably emerge from this two-year study.

The final results from the six-month exposure of ethyl acrylate to rats, however, is of greater concern. Hyperplasia was observed in addition to the metaplasia. Whether the hyperplasia is related to neoplasia will be determined from future results obtained from this two-year study.

Current Production and Use

A review of the production range (includes importation volumes) statistics for ethyl acrylate (CAS No. 140-88-5) as listed in the

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

initial TSCA Inventory (1977) has shown that between 70 million and 200 million pounds of this chemical was produced/imported in 1977. This production range information does not include any production/importation data claimed as confidential by the person(s) reporting for the TSCA Inventory, nor does it include any information which would compromise Confidential Business Information. The data submitted for the TSCA Inventory, including production range information, are subject to the limitations contained in the Inventory Reporting Regulations (40 CFR 710).

This chemical is used in the manufacture of acrylic paints and polymers, and as a chemical intermediate.

Comments/Recommendations

A production and use profile (PUP) and literature search have been initiated as preliminary steps in considering ethyl acrylate a candidate for a Chemical Hazard Information Profile (CHIP).

(a) The two-year inhalation toxicity studies were initiated in December 1977 and should, therefore, be scheduled for completion in December 1979. The submitter should be requested to provide full copies of the pathology results including test data from the 12-month sacrifices which were scheduled for December 1978 and any subsequent sacrifices from these 24-month inhalation toxicity studies on ethyl acrylate.

(b) Copies of the original submission (8EHQ-1078-0250), the followup supplemental submission (8EHQ-0879-0250 Followup Response A) and their respective status reports should be transmitted to OSHA, NIOSH, CPSC, FDA, NCI, and FIB/OWWM.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 19 1979

8EHQ-0879-0251
Supplement
Page 1 of 1

DATE: Revised (May 28, 1980)

SUBJECT: Status Report* 8EHQ-0879-0251
Supplement

Approved ______

Revision Needed ______

FROM: Frank D. Kover, Acting Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division, OTE

Submission Description

This supplemental submission by the Union Carbide Corporation, contains the final report of a life-time skin-painting study with 2',2'-di(sec-butoxy) acetophenone (DBAP; CAS No. 68109-57-9) in mice. The original submission (8EHQ-1078-0251) which summarized this study was received earlier by the Agency and a status report was prepared at that time. Both the original and supplemental submissions state that DBAP had been shown to have a weak tumorigenic activity in mice.

Submission Evaluation

The supplemental information does not alter the impression that DBAP is a weak carcinogen. Because this chemical is photosensitive, there is also a concern for non-cancerous skin lesions in humans.

Current Production and Use

DBAP was developed as a photoinitiator in acrylate-based photocure coating systems. The submitter has previously stated that they have withdrawn from the photocure chemical coatings market. No additional information on current production or other uses for this chemical was located in the secondary sources consulted. However, DBAP is listed in the TSCA Inventory.

Comments/Recommendations

A production and use profile (PUP) and a literature search have been initiated as preliminary steps in considering DBAP a candidate for a Chemical Hazard Information Profile (CHIP).

A copy of this submission and status report should be transmitted to NIOSH, OSHA, CPSC, OWWM.

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

PA FORM 1320-6 (REV. 3-76)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 13 1979

8EHQ-1079-0262
Followup Response
Page 1 of 2

Approved ________

Revision
Needed ________

DATE: Revised (May 28, 1980)

SUBJECT: Status Report* 8EHQ-1079-0262
Follow up Response

FROM: Frank D. Kover, Chief
Chemical Hazard Identification Branch

TO: Joseph J. Merenda, Director
Assessment Division, OTE

Submission Description

The Union Carbide Corporation has provided final results from a mouse life-time skin painting study designed to evaluate the carcinogenic potential of 2-ethylhexyl acrylate (CAS No. 103-11-7). The results indicate that upon repeated (3 times per week) paintings of 2-ethlyhexyl acrylate (75% w/v dilution in acetone) 6/40 mice developed neoplastic skin lesions in the treated area. Histological examination revealed that 4 of the lesions were squamous cell papillomas and 2 were squamous cell carcinomas. It is also reported that a squamous cell carcinoma had developed near the right eye of one of the control mice treated with undiluted acetone. The submission reports that this lesion may or may not have been due to the acetone treatment.

The original submission (8EHQ-1278-0262) had reported that, after 21 months of 2-ethylhexyl acrylate treatment, 31 of 40 treated mice had died, of which 3 were observed to have developed squamous cell papillomas in the treated area. The submitter concluded at that time that the preliminary results indicated a weak tumorigenic activity for 2-ethylhexyl acrylate in mice. However, the submitter also concluded that these preliminary "results, of themselves do not indicate that similar effects would result in humans or necessarily present evidence of a substantial risk to human health."

Submission Evaluation

The final pathology results from this life-time skin-painting study in mice demonstrate that 2-ethylhexyl acrylate is an animal carcinogen.

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on incomplete information.

Current Production and Use

A review of the production range (includes importation volumes) statistics for 2-ethylhexyl acrylate (CAS No. 103-11-7) as listed in the initial TSCA Inventory (1977) has shown that between 21 million and 110 million pounds of this chemical were produced/imported in 1977. This production range information does not include any production/importation data claimed as confidential by the person(s) reporting for the TSCA Inventory, nor does it include any information which would compromise Confidential Business Information. The data submitted for the TSCA Inventory, including production range information, are subject to the limitations contained in the Inventory Reporting Regulations (40 CFR 710).

2-Ethylhexyl acrylate is used as a monomer for plastics, protective coatings, and in paper treatment. It also has uses in water-based paints.

Comments/Recommendations

A Chemical Hazard Information Profile (CHIP) on 2-ethylhexyl acrylate is being prepared by the Chemical Hazard Identification Branch.

Copies of the original submission, the followup submission and the respective status reports should be transmitted to OSHA, NIOSH, NCI, CPSC, FDA, OWWM, and TRDB.

APPENDIX A

THURSDAY, MARCH 16, 1978
PART V

federal register

THE NATIONAL ARCHIVES OF THE UNITED STATES • 1934 •

ENVIRONMENTAL PROTECTION AGENCY

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TOXIC SUBSTANCES CONTROL ACT

Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk

[6560-01]

ENVIRONMENTAL PROTECTION AGENCY

[FRL 849-2]

TOXIC SUBSTANCES CONTROL ACT

Notification of Substantial Risk Under Section 8(e)

AGENCY: Environmental Protection Agency.

ACTION: Statement of interpretation and enforcement policy.

SUMMARY: This action states EPA's interpretation of, and enforcement policy concerning, section 8(e) of the Toxic Substances Control Act (TSCA) (90 Stat. 2029, 15 U.S.C. 2607). The provisions of that section went into effect on January 1, 1977.

Section 8(e) states that "any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information."

DATES: The policy expressed in this document is in effect as of the date of publication.

FOR FURTHER INFORMATION CONTACT:

Frank D. Kover, Assessment Division, Office of Toxic Substances (WH-557), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460, 202-755-2110.

SUPPLEMENTARY INFORMATION: On September 9, 1977, the Agency proposed guidance (42 FR 45362) on its interpretation of and policy concerning the provisions of section 8(e). Although the proposed "guidance" was an interpretive rule and statement of policy exempt from the notice and public comment provisions of the Administrative Procedure Act (5 U.S.C. 553), the Agency solicited comments on several issues to make more informed decisions. On October 11, the comment period was extended from October 15 to October 31, 1977 (42 FR 54857). On November 4, 1977, a supplemental notice to the proposed guidance was published (42 FR 57744), deleting the November 15 date for reporting certain information obtained before 1977 and stating that a new date would be established in the final guidance.

In developing this policy statement, two meetings have been held (February 1, 1977, and October 26, 1977) with selected representatives of industry and environmental and other interested groups. Comments submitted pursuant to the February 1 meeting were addressed in the preamble to the September 9 proposal. Over 100 written comments have been submitted pursuant to the September 9 proposal from trade associations, businesses, environmental groups, labor unions, State and Federal agencies, and other interested parties. Appendix B describes significant issues raised in these comments and the Agency's response to them.

The major modifications to the September 9 proposal are summarized in points 1 through 7 below.

(1) Pursuant to some question over the definition and nature of "guidance," this document is now described more accurately as a "policy statement." It is exempt from the notice and public comment provisions of the Administrative Procedure Act, as well as provisions concerning delayed effective dates.

(2) Many commenters expressed the view that to apply these requirements to officers and employees of a business organization would result in ill-considered, premature reports and would unfairly subject employees to conflicting responsibilities as individual respondents and as corporate agents. Other commenters expressed support for the view that certain employees have a responsibility to report pertinent information, and felt that the phrase "capable of appreciating pertinent information" appropriately described those employees.

The September 9 proposal would have applied section 8(e) requirements to commercial establishments as well as to employees capable of appreciating pertinent information, but stipulated enforcement priorities intended to encourage corporate processing and centralized reporting of such information (42 FR 45363). The intent was to ensure that pertinent information obtained by employees is promptly and appropriately considered, while minimizing duplicative or ill-considered submissions.

The Agency now feels that these objectives would best be served by allowing commercial establishments—under certain conditions designed to ensure full disclosure—to assume exclusive responsibility for reporting to EPA any substantial-risk information obtained by individual officers or employees. Accordingly, this policy statement stipulates that individual officers and employees will have fully discharged their section 8(e) obligations once they have notified the designated responsible company supervisor or official of pertinent information, *provided*, that the employing company or firm has established, internally publicizes, and affirmatively implements procedures governing such notifications. These procedures, at a minimum, must: (1) Specify the information that must be reported; (2) indicate how the notifications are to be prepared and submitted; (3) note the Federal penalties for failing to report; and (4) provide a mechanism for promptly notifying officers and employees who have submitted reports of the company's disposition of those reports, including whether or not they were submitted to EPA (and if not, informing employees of their right to report to EPA, as protected by TSCA section 23). EPA believes these four criteria will ensure prompt and appropriate processing of pertinent information.

Establishment of such procedures notwithstanding, all officials responsible and having authority for the organization's execution of its section 8(e) obligations retain personal liability for ensuring that substantial-risk information is reported to EPA.

(3) The September 9 proposal stated, in Part III, that a person obtains information when he is aware that it "may suggest" substantial risk. Numerous commenters questioned the Administrator's authority to compel the reporting of information which "may suggest" substantial risk. The Administrator agrees that section 8(e) addresses information that "reasonably supports the conclusion" of substantial risk and has deleted the "may suggest" provision, but emphasizes that "reasonably supports the conclusion" of substantial risk is not identical to a conclusive demonstration of substantial risk. The former typically occurs, and must be reported, at an earlier stage. Part VI in this policy statement provides Agency interpretation of the types of information that "reasonably support" such a conclusion.

(4) Numerous commenters requested clarification of different aspects of Part V of the September 9 proposal ("Information Which Reasonably Supports a Conclusion of Substantial Risk"), particularly concerning environmental effects, and suggested different interpretations of what constitutes a "substantial risk". The Agency continues to focus in this policy statement on the effects set forth in the September 9 proposal, but clarifies that the substantiality of a risk is a function of both the seriousness of the effect and the probability of its occurrence (see Part V).

(5) Numerous commenters maintained that section 8(e) only applies prospectively to information obtained after January 1, 1977. The Agency disagrees, as explained in the preamble to the September 9 proposal. This policy statement continues to apply section 8(e) to information obtained before 1977 of which a person has

been aware since January 1, 1977. In response to requests for clarification, the statement defines what constitutes such awareness. In this manner, EPA intends to limit the need for searches of historical records and files.

(6) This policy statement now provides that any information published in scientific literature, in any language, is exempt if it is referred to in abstracts published by specified abstracting services.

(7) This policy statement describes in a new Part X how to submit claims of confidentiality.

Accordingly, the Administrator's interpretation of and policy towards section 8(e) is set forth below.

Dated: February 24, 1978.

Douglas Costle
Administrator.

I. Definitions

The definitions set forth in TSCA section 3 apply to these requirements. In addition, the following definitions are provided for purposes of this policy statement:

The term "manufacture or process 'for commercial purposes' " means to manufacture or process: (1) For distribution in commerce, including for test marketing purposes, (2) for use as a catalyst or an intermediate, (3) for the exclusive use by the manufacturer or processor, or (4) for product research and development.

The term "person" includes any natural person, corporation, firm, company, joint-venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, any municipality, any interstate body and any department, agency, or instrumentality of the Federal Government.

The term "substantial-risk information" means information which reasonably supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.

II. Persons Subject to the Requirement

Persons subject to section 8(e) requirements include both natural persons and business entities engaged in manufacturing, processing, or distributing in commerce a chemical substance or mixture. In the case of business entities, the president, chief executive officer, and any other officers responsible and having authority for the organization's execution of its section 8(e) obligations must ensure that the organization reports substantial-risk information to EPA. The business organization is considered to have obtained any information which any officer or employee capable of appreciating the significance of that information has obtained. It is therefore incumbent upon business organizations to establish procedures for expeditiously processing pertinent information in order to comply with the schedule set forth in Part IV.

Those officers and employees of business organizations who are capable of appreciating the significance of pertinent information are also subject to these reporting requirements. An employing organization may relieve its individual officers and employees of any responsibility for reporting substantial-risk information directly to EPA by establishing, internally publicizing, and affirmatively implementing procedures for employee submission and corporate processing of pertinent information. These procedures, at a minimum, must: (1) Specify the information that officers and employees must submit; (2) indicate how such submissions are to be prepared and the company official to whom they are to be submitted; (3) note the Federal penalties for failing to report; and (4) provide a mechanism for promptly advising officers and employees in writing of the company's disposition of the report, including whether or not the report was submitted to EPA (and if not informing employees of their right to report to EPA, as protected by TSCA section 23). An employee of any company that has established and publicized such procedures, who has internally submitted pertinent information in accordance with them, shall have discharged his section 8(e) obligation. Establishment of such procedures notwithstanding, all officials responsible and having authority for the organization's execution of its section 8(e) obligations retain personal liability for ensuring that the appropriate substantial-risk information is reported to EPA.

Business organizations that do not establish such procedures cannot relieve their individual officers and employees of the responsiblity for ensuring that substantial-risk information they obtain is reported to EPA. While officers and employees of such organizations may also elect to submit substantial-risk information to their superiors for corporate processing and reporting, rather than to EPA directly, they have not discharged their individual section 8(e) obligation until EPA has received the information.

Note.—Irrespective of a business organization's decision to establish and publicize the procedures described above, it is responsible for becoming cognizant of any substantial-risk information obtained by its officers and employees, and for ensuring that such information is reported to EPA within 15 working days.

III. When a Person Will Be Regarded as Having Obtained Information

A person obtains substantial-risk information at the time he first comes into possession of or knows of such information.

Note.—This includes information of which a prudent person similarly situated could reasonably be expected to possess or have knowledge.

An establishment obtains information at the time any officer or employee capable of appreciating the significance of such information obtains it.

IV. Requirement That a Person "Immediately Inform" the Administrator

With the exception of information on emergency incidents of environmental contamination [see Part V(c)] a person has "immediately informed" the Administrator if information is received by EPA not later than the 15th working day after the date the person obtained such information. Supplementary information generated after a section 8(e) notification should, if appropriate, be immediately reported. For emergency incidents of environmental contamination, a person shall report the incident to the Administrator by telephone as soon as he has knowledge of the incident (see Part IX for appropriate telephone contacts). The report should contain as much of the information required by Part IX as possible. A written report in accordance with Part IX (a) through (f) is to be submitted within 15 days.

Information currently in the possession of a person who is subject to reporting must be reported within 60 days of publication of this policy statement.

V. What Constitutes Substantial Risks

A "substantial risk of injury to health or the environment" is a risk of considerable concern because of (a) the seriousness of the effect [see Subparts (a), (b), and (c) below for an illustrative list of effects of concern], and (b) the fact or probability of its occurrence. (Economic or social benefits of use, or costs of restricting use, are not to be considered in determining whether a risk is "substantial".) These two criteria are differentially weighted for different types of effects. The human health effects listed in Subpart (a) below, for example, are so serious that relatively little weight is given to exposure; the mere fact the implicated chemical is in commerce constitutes sufficient evidence of exposure. In contrast, the remaining effects listed in Subparts (b) and (c) below must involve, or be accompanied by the potential for, significant levels of exposure (because of general production levels, persistence, typical uses, common means of disposal, or other pertinent factors).

Note that: (i) The effects outlined below should not be reported if the respondent has actual knowledge that the Administrator is already informed of them.

(ii) Information respecting these effects can be obtained either directly, by observation of their occurrence, or inferred from designed studies as discussed in Part VI.

The Agency considers effects for which substantial-risk information must be reported to include the following:

(a) *Human health effects*—(1) Any instance of cancer, birth defects, mutagenicity, death, or serious or prolonged incapacitation, including the loss of or inability to use a normal bodily function with a consequent relatively serious impairment of normal activities, if one (or a few) chemical(s) is strongly implicated.

(2) Any pattern of effects or evidence which reasonably supports the conclusion that the chemical substance or mixture can produce cancer, mutation, birth defects or toxic effects resulting in death, or serious or prolonged incapacitation.

(b) *Environmental effects*—(1) Widespread and previously unsuspected distribution in environmental media, as indicated in studies (excluding materials contained within appropriate disposal facilities).

(2) Pronounced bioaccumulation. Measurements and indicators of pronounced bioaccumulation heretofore unknown to the Administrator (including bioaccumulation in fish beyond 5,000 times water concentration in a 30-day exposure or having an n-octanol/water partition coefficient greater than 25,000) should be reported when coupled with potential for widespread exposure and any non-trivial adverse effect.

(3) Any non-trivial adverse effect, heretofore unknown to the Administrator, associated with a chemical known to have bioaccumulated to a pronounced degree or to be widespread in environmental media.

(4) Ecologically significant changes in species' interrelationships; that is, changes in population behavior, growth, survival, etc. that in turn affect other species' behavior, growth, or survival.

Examples include: (i) Excessive stimulation of primary producers (algae, macrophytes) in aquatic ecosystems, e.g., resulting in nutrient enrichment, or eutrophication, of aquatic ecosystems.

(ii) Interference with critical biogeochemical cycles, such as the nitrogen cycle.

(5) Facile transformation or degradation to a chemical having an unacceptable risk as defined above.

(c) *Emergency incidents of environmental contamination*—Any environmental contamination by a chemical substance or mixture to which any of the above adverse effects has been ascribed and which because of the pattern, extent, and amount of contamination (1) seriously threatens humans with cancer, birth defects, mutation, death, or serious or prolonged incapacitation, or (2) seriously threatens non-human organisms with large-scale or ecologically significant population destruction.

VI. NATURE AND SOURCES OF INFORMATION WHICH "REASONABLY SUPPORTS THE CONCLUSION" OF SUBSTANTIAL RISK

Information attributing any of the effects described in Part V above to a chemical substance or mixture is to be reported if it is one of the types listed below and if it is not exempt from the reporting requirement by reason of Part VII of this policy statement. A person is not to delay reporting until he obtains conclusive information that a substantial risk exists, but is to immediately report any evidence which "reasonably supports" that conclusion. Such evidence will generally not be conclusive as to the substantiality of the risk; it should, however, reliably ascribe the effect to the chemical.

Information from the following sources concerning the effects described in Part V will often "reasonably support" a conclusion of substantial risk. Consideration of corroborative information before reporting can only occur where it is indicated below.

(1) *Designed, controlled studies.* In assessing the quality of information, the respondent is to consider whether it contains reliable evidence ascribing the effect to the chemical. Not only should final results from such studies be reported, but also preliminary results from incomplete studies where appropriate. Designed, controlled studies include:

(i) In vivo experiments and tests.

(ii) In vitro experiments and tests. Consideration may be given to the existence of corroborative information, if necessary to reasonably support the conclusion that a chemical presents a substantial risk.

(iii) Epidemiological studies.

(iv) Environmental monitoring studies.

(2) *Reports concerning and studies of undesigned, uncontrolled circumstances.* It is anticipated here that reportable effects will generally occur in a pattern, where a significant common feature is exposure to the chemical. However, a single instance of cancer, birth defects, mutation, death, or serious incapacitation in a human would be reportable if one (or a few) chemical(s) was strongly implicated. In addition, it is possible that effects less serious than those described in Part V(a) may be preliminary manifestations of the more serious effects and, together with another triggering piece of information, constitute reportable information; an example would be a group of exposed workers experiencing dizziness together with preliminary experimental results demonstrating neurological dysfunctions.

Reports and studies of undesigned circumstances include:

(i) Medical and health surveys.

(ii) Clinical studies.

(iii) Reports concerning and evidence of effects in consumers, workers, or the environment.

VII. INFORMATION WHICH NEED NOT BE REPORTED

Information need not be reported if it:

(a) Has been published by EPA in reports;

(b) Has been submitted in writing to EPA pursuant to mandatory reporting requirements under TSCA or any other authority administered by EPA (including the Federal Insecticide, Fungicide and Rodenticide Act, the Clean Air Act, the Federal Water Pollution Control Act, the Marine Protection, Research, and Sanctuaries Act, the Safe Drinking Water Act, and the Resource Conservation and Recovery Act), provided that the information: (1) Encompasses that required by Part IX (c) through (f); and (2) is from now on submitted within the time constraints set forth in Part IV and identified as a section 8(e) notice in accordance with Part IX(b);

(c) Has been published in the scientific literature and referenced by the following abstract services: (1) Agricola, (2) Biological Abstracts, (3) Chemical Abstracts, (4) Dissertation Abstracts, (5) Index Medicus, (6) National Technical Information Service.

(d) Is corroborative of well-established adverse effects already documented in the scientific literature and referenced as described in (c) above, unless such information concerns emergency incidents of environmental contamination as described in Part V(c), or

(e) Is contained in notification of spills under section 311(b)(5) of the Federal Water Pollution Control Act.

VIII. INFORMATION FIRST RECEIVED BY A PERSON PRIOR TO THE EFFECTIVE DATE OF TSCA

Any substantial risk information possessed by a person prior to January 1, 1977, of which he is aware after that date shall be reported within 60 days of publication of this policy statement. The Agency considers that a person is "aware" of:

(a) Any information reviewed after January 1, 1977, including not only written reports, memoranda and other documents examined after January 1, 1977, but also information referred to in discussions and conferences in which the person participated after January 1, 1977;

(b) Any information the contents of which a person has been alerted to by date received after January 1, 1977, including any information concerning a chemical for which the person is presently assessing health and environmental effects;

(c) Any other information of which the person has actual knowledge.

IX. REPORTING REQUIREMENTS

Notices shall be delivered to the Document Control Officer, Chemical Information Division, Office of Toxic Substances (WH-557), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460.

A notice should:

(a) Be sent by certified mail, or in any other way permitting verification of its receipt by the Agency,

(b) State that it is being submitted in accordance with section 8(e),

(c) Contain the job title, name, address, telephone number, and signature of the person reporting and the name and address of the manufacturing, processing, or distributing establishment with which he is associated,

(d) Identify the chemical substance or mixture (including, if known, the CAS Registry Number),

(e) Summarize the adverse effects being reported, describing the nature and the extent of the risk involved, and

(f) Contain the specific source of the information together with a summary and the source of any available supporting technical data.

For emergency incidents of environmental contamination (see Part V(c)), a person shall report the incident to the Administrator by telephone as soon as he has knowledge of the incident (see below for appropriate telephone contacts). The report should contain as much of the information required by instructions (b) through (f) above as possible. A written report, in accordance with instructions (a) through (f) above, is to be submitted within 15 days. Twenty-four hour emergency telephone numbers are:

Region I (Maine, Rhode Island, Connecticut, Vermont, Massachusetts, New Hampshire), 617-223-7265.
Region II (New York, New Jersey, Puerto Rico, Virgin Islands), 201-548-8730.
Region III (Pennsylvania, West Virginia, Virginia, Maryland, Delaware, District of Columbia), 215-597-9898.
Region IV (Kentucky, Tennessee, North Carolina, South Carolina, Georgia, Alabama, Mississippi, Florida), 404-881-4062.
Region V (Wisconsin, Illinois, Indiana, Michigan, Ohio, Minnesota), 312-353-2318.
Region VI (New Mexico, Texas, Oklahoma, Arkansas, Louisiana), 214-749-3840.
Region VII (Nebraska, Iowa, Missouri, Kansas), 816-374-3778.
Region VIII (Colorado, Utah, Wyoming, Montana, North Dakota, South Dakota), 303-837-3880.
Region IX (California, Nevada, Arizona, Hawaii, Guam), 415-556-6254.
Region X (Washington, Oregon, Idaho, Alaska), 206-442-1200.

X. CONFIDENTIALITY CLAIMS

(a) Any person submitting a notice to EPA under section 8(e) of TSCA may assert a business confidentiality claim covering all or part of the information contained in the notice. Any information covered by a claim will be disclosed by EPA only to the extent, and by means of the procedures, set forth in 40 CFR Part 2 (41 FR 36902, September 1, 1976).

(b) If no claim accompanies the notice at the time it is submitted to EPA, the notice will be placed in an open file to be available to the public without further notice to the submitter.

(c) To assert a claim of confidentiality for information contained in a notice, the submitter must submit two copies of the notice.

(1) One copy must be complete. In that copy the submitter must indicate what information, if any, is claimed as confidential by marking the specified information on each page with a label such as "confidential," "proprietary," or "trade secret."

(2) If some information in the notice is claimed as confidential, the submitter must submit a second copy. The second copy must be complete except that all information claimed as confidential in the first copy must be deleted.

(3) The first copy of the notice will be disclosed by EPA only to the extent, and by means of the procedures, set forth in 40 CFR Part 2. The second copy will be placed in an open file to be available to the public.

(d) Any person submitting a notice containing information for which they are asserting a confidentiality claim should send the notice in a double envelope.

(1) The outside envelope should bear the same address outlined in section IX of this policy statement.

(2) The inside envelope should be clearly marked "To be opened only by the OTS Document Control Officer."

XI. FAILURE TO REPORT INFORMATION

Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to submit information required under section 8(e). Section 16 provides that a violation of section 15 renders a person liable to the United States for a civil penalty and possible criminal prosecution. Pursuant to section 17, the Government may seek judicial relief to compel submittal of section 8(e) information and to otherwise restrain any violation of section 8(e).

APPENDIX A.—QUICK REFERENCE SUMMARY FOR EMERGENCY INCIDENTS OF ENVIRONMENTAL CONTAMINATION

A. WHAT SHOULD BE REPORTED AS AN EMERGENCY INCIDENT

An emergency incident of environmental contamination is "any environmental contamination by a chemical substance or mixture . . . which, because of the pattern, extent and amount of contamination, (1) Seriously threatens humans with cancer, birth defects, mutation, death, or serious or prolonged incapacitation, or (2) seriously threatens non-human organisms with large scale or ecologically significant population destruction". (See Part V(c) for complete description.)

B. WHAT NEED NOT BE REPORTED AS AN EMERGENCY INCIDENT

Information contained in notification of spills under section 311(b)(5) of the Federal Water Pollution Control Act (FWPCA). (For a complete list of exemptions to reporting, see Part VII.)

C. WHEN AND WHERE TO REPORT EMERGENCY INCIDENTS

Emergency incidents of environmental contamination are to be reported immediately by telephone to the appropriate EPA Regional 24-hour telephone emergency line listed below.

Region I (Maine, Rhode Island, Connecticut, Vermont, Massachusetts, New Hampshire), 617-223-7265.
Region II (New York, New Jersey, Puerto Rico, Virgin Islands), 201-548-8730.
Region III (Pennsylvania, West Virginia, Virginia, Maryland, Delaware, District of Columbia), 215-597-9898.
Region IV (Kentucky, Tennessee, North Carolina, South Carolina, Georgia, Alabama, Mississippi, Florida), 404-881-4062.
Region V (Wisconsin, Illinois, Indiana, Michigan, Ohio, Minnesota), 312-353-2318.
Region VI (New Mexico, Texas, Oklahoma, Arkansas, Louisiana), 214-749-3840.
Region VII (Nebraska, Iowa, Missouri, Kansas), 816-374-3778.
Region VIII (Colorado, Utah, Wyoming, Montana, North Dakota, South Dakota), 303-837-3880.
Region IX (California, Nevada, Arizona, Hawaii, Guam), 415-556-6254.
Region X (Washington, Oregon, Idaho, Alaska), 206-442-1200.

In addition, a written report, in accordance with instructions (a) through (f) of Part IX, is to be submitted within 15 days to the Document Control Officer, Chemical Information Division, Office of Toxic Substances (WH-557), 401 M Street SW., Washington, D.C. 20460.

APPENDIX B—SIGNIFICANT COMMENTS AND RESPONSES

A. PERSONS SUBJECT TO THESE REQUIREMENTS

Comment 1: Employees cannot be held subject to these requirements, since: (a) They only have a partial role in the manufacture, processing, or distribution of chemicals, (b) in other sections of TSCA, the term "person who manufactures, processes, or distributes" chemicals clearly refers to business organizations; "persons" should be consistently defined, and (c) the application of criminal penalties mandates a strict interpretation of this word.

Response: The Agency considers that different sections of TSCA, having different purposes, are appropriately directed to different respondents. In the case of section 8(e), officers and employees who are capable of appreciating the significance of information have a legitimate responsibility to be alert to and report substantial-risk information. The guidance has been modified so that natural persons and business entities can fulfill their section 8(e) obligations in different ways. Most officers and employees can discharge their section 8(e) obligations by submitting pertinent information to corporate superiors, provided that the company has established the risk-evaluation procedures characterized in Part II. In the case of a business organization, its president, chief executive officer, and other officials responsible and having authority for the business organization's execution of its section 8(e) obligations must ensure that the organization reports substantial-risk information to EPA.

Comment 2: Even if employees can be held subject to these requirements, they should not be. To do so would force employees and employers into conflicting positions, inviting internal corporate dissension and over-reporting. Further, individuals often do not have the overview necessary to reach considered, well-supported decisions. Corporate reporting by designated officials will provide EPA with more reliable data.

Response: The Agency considers that employees have a legitimate role in risk reporting; it is imperative that risk information obtained by employees be appropriately considered. Officers and employees can fulfill their role in the reporting of substantial-risk information, without the disadvantages described above, by reporting information to superiors for corporate consideration, and, having done so, will have discharged their obligation to EPA. This is contingent upon the establishment by the business organization of certain procedures for risk-evaluation, thereby assuring the appropriate consideration of such reports. Those officers responsible and having authority for the organization's execution of its section 8(e) obligations must ensure that the organization reports substantial-risk information to EPA.

Comment 3: Clarify which employees are covered, and the extent of their obligation. Are employees "capable of appreciating pertinent information" by virtue of rank, or knowledge? Are rank and file employees subject to these requirements, or just supervisory and managerial personnel, company toxicologists, etc.? Is an employee absolved of further responsibility if he reports to his supervisor?

Response: The Agency considers that the phrase "capable of appreciating the significance of pertinent information" appropriately describes those officers and employees who have a responsibility to be alert to and report substantial-risk information, including not only relatively senior corporate officers but also many corporate employees. The policy statement modifies the September 9 proposal, in response to the concerns expressed in Comments 2 and 3, to permit most officers and employees to discharge their obligation by submitting information to corporate superiors, subject to the conditions described in Part II.

Comment 4: Consultants and independent labs should not be subject to these requirements.

Response: Contractors and independent labs are not responsible for reporting information they have obtained directly to EPA; rather, their client manufacturers, processors and distributors are responsible for reporting such information.

B. THE "OBTAINING" OF INFORMATION

Comment 5: The "may suggest" criterion in Part III of the proposal serves to compel further examination of information that by itself is not subject to section 8(e) requirements. The statutory language calling for "reasonable support" does not support this. Further, risk assessment often requires anywhere from months to several years of study after preliminary results "suggest" risk, far exceeding the 15-day compliance period.

Response: The Agency does not intend to compel under section 8(e) examination of information that by itself is not subject to section 8(e) requirements and has deleted the "may suggest" provision, providing its interpretation of what constitutes evidence that "reasonably supports the conclusion" of substantial risk in a new Part VI.

Comment 6: Section 8(e) obligations are incurred upon obtaining conclusory substantial-risk information.

Response: The Agency disagrees, and considers that "reasonable support" of a conclusion of substantial risk is not identical to the conclusion itself. The former typically occurs, and must be reported, at an earlier stage.

Comment 7: The statement, in Part III of the proposal that a person has obtained information if he ". . . should know of the existence of such information not in his possession but which would be delivered to him on request," tends to compel an active search for substantial-risk information rather than the reporting of substantial-risk information a person "obtains." This is of particular concern to importers with limited access to information possessed by their suppliers.

Response: The Agency considers that section 8(e) applies to information which a person possesses or of which he knows. It is not intended to compel searches for information or extraordinary efforts to acquire information. The Agency further considers, however, that "known" information includes information which a prudent person similarly situated could reasonably be expected to know. Negligence or intentional avoidance of information does not absolve a person of his section 8(e) obligation. Part III has been modified to express these intentions.

Comment 8: Circumstances can exist when coming "into possession" of risk information does not correspond to an understanding of the implications of the information; "obtains" should be defined in terms of possession of information and awareness of its import.

Response: The "obtaining" of information occurs via persons who are "capable of appreciating the significance of pertinent information." There will likely be circumstances in which the evaluation of information clarifies its full import; the establishment of corporate procedures for processing risk-information prescribed in Part II will expedite this.

C. TIME ALLOWED FOR COMPLIANCE

Comment 9: Fifteen calendar days is insufficient to determine whether information which "may suggest" substantial risk should be reported; it is even insufficient to accommodate normal procedural time constraints (corporate processing, mailing, holidays, etc.).

Response: The Agency has changed the compliance period to 15 business days. It is imperative that procedures be established to expedite the reporting of substantial-risk information, not that reporting conform to existing procedures.

Comment 10: Allow from 30 to 90 days for the second phase of reporting; alternatively, do not prescribe a time limit for additional reporting.

Response: Having deleted the "may suggest" criterion, the Agency sees no need to provide a second phase to the reporting period. Supplemental information that is generated after a section 8(e) notification should, if appropriate, be immediately reported.

Comment 11: Allow from 30 to 120 days to report pre-1977 information; this period should commence: (a) upon final publication, (b) January 1, 1978, (c) following the inventory reporting period since many of the same corporate personnel will be implementing both requirements.

Response: The policy statement prescribes a 60 day reporting period, commencing immediately upon publication. Section 8(e) has been in effect since January 1, 1977; postponement in reporting substantial-risk information is not warranted.

D. EFFECTS AND INFORMATION THAT MUST BE REPORTED

Comment 12: The reporting of "any instance" of cancer, birth defects, etc., in humans is too broad and such information will be of little use; chemical workers, like the general population, develop cancers and other ailments of uncertain etiology.

Response: This policy statement clarifies that the reporting of single occurrences of human cancer or other serious effects will depend upon evidence strongly implicating one (or a few) chemical(s).

Comment 13: Dermal ailments and nausea are poorly chosen examples of precursor symptoms. Deleting these examples will avoid unduly emphasizing them when other symptoms may be more important, yet will not eliminate the obligation to report them if they are suspected precursors.

Response: The Agency agrees.

Comment 14: How are reportable data distinguished from routine tests including range tests such as LD$_{50}$'s?

Response: This policy statement directs the reporting of specified effects when unknown to the Administrator. Many routine tests are based on a knowledge of toxicity associated with a chemical; unknown effects occurring during such a range test may have to be reported if they are those of concern to the Agency and if the information meets the criteria set forth in Parts V and VI.

Comment 15: The most widespread "in vitro" test is the Ames test, which is subject to considerable debate. Clarify the circumstances under which positive results of in vitro tests must be reported.

Response: Part VI clarifies that the reporting of in vitro tests will depend upon the existence of corroborative information if necessary to reasonably support the conclusion of substantial risk.

Comment 16: The description of "extreme persistence" as a substantial risk is an example of the need to redefine Part V(c) ("Environmental Effects"). Persistence and bioaccumulation should be considered risks only when coupled with toxicity and significant exposure.

Response: Part V now clarifies those effects for which reporting depends upon a significant exposure potential. Persistence by itself is no longer itemized as a reportable effect but rather is considered to be a component of exposure potential; it may also underlie the measurements described in Part V(b)(1). Laboratory indicators of pronounced bioaccumulation are to be reported when coupled with potential for widespread exposure and any non-trivial adverse effect.

Comment 17: The n-octanol/water partition coefficient addresses a physico-chemical property, not biological effects, and is not alone an indicator of substantial risk; further, the values stated for the coefficient and the bioaccumulation factor in fish do not correspond.

Response: The Agency acknowledges the numerical error and has amended the values to correspond. This policy statement now directs the reporting of an experimental measurement of bioaccumulation when coupled with an adverse effect and potential for widespread exposure.

Comment 18: The requirement that information which "links" an effect to a chemical be reported is too broad and contradicts the statutory language of "reasonably supports".

Response: The Agency has provided in a new Part VI its interpretation of "reasonably supports".

Comment 19: A determination that information "reasonably supports the conclusion" of substantial risk cannot be made independently of considerations of use since the method and manner of using a chemical may influence the occurrence of an effect; in particular, the criteria should reflect a distinction between normal and abnormal uses of chemicals.

Response: The Agency considers that the appropriate components of a "substantial risk" with respect to a chemical are (a) the seriousness of the effect, and (b) total exposure potential. The method and manner of using a chemical is one of several factors determining its exposure potential. As described in Part V, the importance of exposure potential as a component of "substantial risk" depends upon the kind of effect of concern. Thus, the effects described in Part V(a) are so serious that relatively little weight is given to exposure; the effects described in Parts V (b) and (c) involve a significant exposure or exposure potential.

The Agency further considers that a definition of "normal" use for a particular chemical will often depend upon a knowledge of the risks associated with the chemical.

E. INFORMATION THAT NEED NOT BE REPORTED

Comment 20: Information published in scientific literature in languages other than English should be exempted if published in summary form by abstracting services. Can the accuracy of English language abstracts and commercial translations of foreign literature be assumed?

Response: This policy statement now provides that information published in scientific literature, whether in English or another language, is exempt from reporting if published in summary form by certain specified abstract services.

Comment 21: Information exchange systems with other Federal agencies should be immediately established so that respondents need not report to EPA information already reported to other Agencies, and vice versa. Such duplicative reports are unduly burdensome.

Response: EPA is coordinating this program with other agencies now. When this coordination is successfully completed, the policy statement will be amended to exempt from the reporting requirement information that has been submitted to other specified agencies. In the meantime, substantial-risk information must be reported directly to EPA; such a report does not discharge any reporting obligation to other agencies.

F. INFORMATION FIRST RECEIVED PRIOR TO THE EFFECTIVE DATE OF TSCA

Comment 22: The tense of the verb "obtains" reveals that section 8(e) was intended to be applied prospectively to information newly acquired after January 1, 1977. Utilize section 8(d) or other rules to acquire information obtained before then.

Response: As discussed in the preamble to the September 9 proposal, the Agency considers section 8(e) to apply to risk information possessed by or known to a person before, on, or after January 1, 1977. Concerning information first obtained before 1977, this policy statement continues to require reporting of information received if a person has been aware of it since January 1, 1977, for the reasons discussed in the September 9 preamble.

Comment 23: The term "aware" is too vague to be of any help in responding to these requirements. Since many corporate employees are potentially subject to these requirements, and given uncertainty over the extent to which they ought to be aware of pre-1977 information, this provision tends to compel the very file search it was intended to avoid. The term "aware" should be further defined, possibly in terms of actual knowledge.

Response: The Agency in Part VIII of this policy statement now defines the pre-1977 information of which a person is considered to be aware.

G. CONFIDENTIAL INFORMATION

Comment 24: EPA should delay guidance until procedures are published governing the treatment of confidential submissions.

Comment 25: EPA should treat all submissions as confidential until the information is verified.

Comment 26: EPA should automatically publish section 8(e) notices.

Response to Comments 24 through 26: EPA has included a new Part X which describes how to submit a claim of confidentiality and states that any or all of the information submitted may be claimed as confidential. Such information will be disclosed by EPA only to the extent, and by means of the procedures, set forth in 40 CFR Part 2.

H. MISCELLANEOUS

Comment 27: What is the statutory basis or need for guidance? What is its exact status under the Administrative Procedure Act?

Response: This policy statement sets forth EPA's interpretation of and policy concerning TSCA section 8(e). As an interpretive rule and statement of policy it is not subject to the comment period and delayed effective date provisions of the Administrative Procedure Act (5 U.S.C. 553). Although TSCA does not mandate a policy statement, the Agency of necessity must develop the criteria which will govern enforcement activities. Trade associations and businesses were among those who previously expressed interest in such a statement to guide their compliance.

Comment 28: Clarify whether these requirements apply to chemicals previously but no longer manufactured, processed, or distributed in commerce by a person.

Response: Information obtained before 1977 must be reported if the person has been aware of it since January 1, 1977, as prescribed by Part VIII. Concerning chemicals which a person has discontinued manufacturing, processing, or distributing since January 1, 1977, information obtained before the time of discontinuation is subject to these requirements. It is expected that the acquisition of information after that time will be minimal; however, should additional information be acquired, it may trigger the reporting described in Part VIII.

Comment 29: Clarify the meaning of "substantial risk" relative to other risks addressed by TSCA.

Response: A substantial risk is defined in Part V(a) of this policy statement as a risk of considerable concern because of (a) the seriousness of the effect, and (b) the fact or probability of its occurrence. As opposed to other risks addressed by TSCA, economic or social benefits of use, or costs of restricting use, are not to be considered in determining whether a risk is "substantial".

Comment 30: To what extent are "users" of chemicals subject to these requirements?

Response: The Agency considers that many industrial uses of chemicals actually fall within the scope of "processing" chemicals. A manufacturer, processor, or distributor who obtains substantial-risk information concerning chemicals he handles should be alert to the possibility he may have to report it.

Comment 31: Are chemicals manufactured, processed and distributed in commerce in small quantities solely for purposes of research and development subject to these requirements?

Response: In general, the Agency considers that much manufacturing, processing, and distribution in commerce of chemicals in small quantities solely for purposes of research and development is conducted for "commercial purposes". Such purposes would include the sale and distribution of such materials, as well as their use by the manufacturer or processor in activities (for example, product research and development and studies assessing the feasibility and safety of using chemicals) preceding his or a client's commercial use of such materials or others on a larger scale.

As described in Part V, the Agency considers that "substantial risks" depend in part upon an exposure potential. Thus, the occurrence of the effects described in Part V(a) presuppose exposure to the chemical and must be reported; reporting of the other effects will depend upon a potential for significant levels of exposure.

Comment 32: Are raw materials, intermediates, and inert ingredients produced or used in the manufacture of a pesticide subject to TSCA?

Response: The Administrator considers that raw materials, intermediates and inert ingredients produced or used in the manufacture of a pesticide are substances or mixtures which can be regulated under TSCA.

In order to be considered a pesticide, a substance must be intended for use as a pesticide. Raw materials, intermediates, and inert ingredients produced or used in the manufacture of a pesticide are not themselves regulated under FIFRA (unless they happen to be pesticides themselves) and, therefore, are subject to TSCA. The pesticide regulations at 40 CFR 162.4 are consistent with this view.

Comment 33: Are intermediates and catalysts intended solely for use in the production of a food, food additive, drug, cosmetic, or device subject to TSCA?

Response: The Administrator considers that intermediates and catalysts intended solely for use in the production of a food, food additive, drug, cosmetic, or device are excluded from regulation under TSCA. The definitions of the FFDCA provide that chemical substances which are intended for use as a component of a food, food additive, drug, cosmetic, or device are encompassed within the meaning of such terms, respectively. The FDA considers intermediates and catalysts to be such components. Therefore, they are subject to regulation under the FFDCA. Any such substance is excluded from regulation under TSCA insofar as it is actually manufactured, processed, or distributed in commerce solely for use in the production of a food, food additive, drug, cosmetic, or device.

Comment 34: Employees should have the option to submit reports anonymously.

Response: EPA considers that any person may report information to EPA under TSCA. Those who are required to do so under section 8(e) are persons who manufacture, process, or distribute in commerce chemical substances or mixtures, including not only business entities but also such employees as described in Part II. In order to establish that such persons have discharged their obligations, and in order to encourage responsible review of the quality of information and the substantiality of risks, EPA believes that notifiers should identify themselves. Section 23 will adequately protect employees from discrimination pursuant to notifications they have made under section 8(e).

[FR Doc. 78-7064 Filed 3-15-78; 8:45 am]

APPENDIX B. STATUS REPORTS BY CHEMICAL NAME

CHEMICAL NAME	SUBMISSION NO.
ACETOPHENONE, 2',2'-DI(SEC-BUTOXY)-	08790251 SUPPLEMENT
ACRYLATE, NEOPENTYLGLYCOL DI-	11790028 SUPPLEMENT
ACRYLIC ACID, ETHYL ESTER	08790250 FOLLOW UP RESPONSE
ACRYLIC ACID, 2-ETHYL HEXYL ESTER	10790262 FOLLOW UP RESPONSE
ACRYLONITRILE	08790300
ALCOHOL ETHOXYSULFATE (AMMONIUM SALT)	09790326
ALCOHOL ETHOXYSULFATE (SODIUM SALT)	09790326
ARCO LB-7979	01800327
ARGUS Q-328 (MARK-328)	10790315 *
ARYL PHOSPHATES	10790317
BENZENE, CHLORO-	09790310 01800330
BENZYLTRIPHENYLPHOSPHONIUM CHLORIDE	07790296
BISPHENOL A-EPICHLOROHYDRIN RESINS	07790292
C. I. DISPERSE BLUE 7 DYE	10790321
CARBOFURAN	07790299 *
CARBON TETRACHLORIDE	09790310

APPENDIX B. STATUS REPORTS BY CHEMICAL NAME (contd.)

CHEMICAL NAME	SUBMISSION NO.
CHLORINE	12790322 * 12790329 *
CHLOROFORM	09790310 01800324
COAL DERIVED FUEL OIL FRACTIONS (EXPERIMENTAL)	09790306 10790316
DIALLYL DIGLYCOL CARBONATE	09790311
DIMETHYLHYDANTOIN - DERIVED EPOXY RESIN (DEVELOPMENTAL)	01800328S
DIOXANE, 1,4-	10790320 09790326
DIRECT BLACK 38 DYE	07790295
EPICHLOROHYDRIN	07790292
ETHANE, 1,1-DICHLORO-	09790310
ETHANE, 1,1,1-TRICHLORO-	09790310
ETHANE, 1,1,2-TRICHLORO-	09790310
ETHANE, 1,2-DICHLORO-	09790310
ETHENE, 1,2-DICHLORO-, (E)	09790310
ETHER, BIS(CHLOROMETHYL)	01800324
ETHOXYLATED PRODUCTS	10790320

APPENDIX B. STATUS REPORTS BY CHEMICAL NAME (contd.)

CHEMICAL NAME	SUBMISSION NO.	
ETHYLENE OXIDE	09790305	
ETHYLENE, TETRACHLORO-	09790310	
ETHYLENE, TRICHLORO-	09790310	
ETHYLENE, 1,1-DICHLORO-	09790310	
ETHYLTRIPHENYLPHOSPHONIUM ACID ACETATE	07790296	
ETHYLTRIPHENYLPHOSPHONIUM IODIDE	07790296	
FORMALDEHYDE	10790314	
FURADAN 10-G (10% GRANULAR)	07790299	*
HOME HEATING OIL (NO.2)	08790301	
HYDROQUINONE MONOMETHYL ETHER	09790311	
ISOPAR C	10790312	
JET FUEL A	12790323	
KRONITEX (R) 100	10790317	
KRONITEX (R) 200	10790317	
KRONITEX (R) 200B	10790317	
KRONITEX (R) 50	10790317	
MALEIC ANHYDRIDE	09790311	

APPENDIX B. STATUS REPORTS BY CHEMICAL NAME (contd.)

CHEMICAL NAME	SUBMISSION NO.	
METHANE, DICHLORO-	01800324	
MORPHOLINE	07790294	
N-ALKYL GLYCIDYL ETHERS (C2-C10)	07790293	
NAPHTHA (PETROLEUM), LIGHT ALKYLATE	10790312	
ORGANIC SOLVENTS	08790304 07790010	* FOLLOW UP RESPONSE
PETROLEUM DISTILLATE (LIGHT CATALYTIC CRACKED)	08790301	
PETROLEUM DISTILLATE (STRAIGHT RUN MIDDLE)	08790301	
PHENOL, DIMETHYL-, PHOSPHATE (3:1)	10790317	
PHENOL, ISOBUTYLENATED, PHOSPHATE (3:1)	10790317	
PHENOL, ISOPROPYLATED, PHOSPHATE (3:1)	10790317	
PHOSPHONIUM ACID COMPOUNDS	07790296	
PHOSPHORIC ACID, TRIPHENYL ESTER	10790317	
PHOSPHORIC ACID, TRITOLYL ESTER	10790317	
POLYCHLORINATED BIPHENYLS	01800330 10790319	
POLYGARD	10790315	*
PROVALENT 4A	01800327	

APPENDIX B. STATUS REPORTS BY CHEMICAL NAME (contd.)

CHEMICAL NAME	SUBMISSION NO.	
SRC-II HEAVY DISTILLATE	07790297	
STRONTIUM CHROMATE	10790318	
TETRABUTYLPHOSPHONIUM ACID ACETATE	07790296	
THIODIPROPIONATE ESTER COMPLEX	10790315	*
s-TRIAZINE-2,4,6-TRITHIOL	12790325	
TRI (MIXED MONO AND DINONYLPHENYL) PHOSPHITE	10790315	*
TRICARBONYL, METHYLCYCLOPENTADIENYL MANGANESE-	10790211	FOLLOW UP RESPONSE
TUNGSTEN HEXACARBONYL	09790311	
VARSOL 40	10790312	

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APPENDIX C. STATUS REPORTS BY CAS REGISTRY NUMBER

CAS NUMBER	SUBMISSION NO.
50-00-0	10790314
56-23-5	09790310
67-66-3	09790310 01800324
71-55-6	09790310
75-09-2	01800324
75-21-8	09790305
75-34-3	09790310
75-35-4	09790310
79-00-5	09790310
79-01-6	09790310
103-11-7	10790262 FOLLOW UP RESPONSE
106-89-8	07790292
107-06-2	09790310
107-13-1	08790300
108-31-6	09790311
108-90-7	09790310 01800330
110-91-8	07790294
115-86-6	10790317

APPENDIX C. STATUS REPORTS BY CAS REGISTRY NUMBER (contd.)

CAS NUMBER	SUBMISSION NO.
123-91-1	10790320 09790326
127-18-4	09790310
140-88-5	08790250 FOLLOW UP RESPONSE
142-22-3	09790311
150-76-5	09790311
156-60-5	09790310
542-88-1	01800324
638-16-4	12790325
1100-88-5	07790296
1330-78-5	10790317
1336-36-3	10790319 01800330
1563-66-2	07790299 *
1937-37-7	07790295
2223-82-7	11790028 SUPPLEMENT
3179-90-6	10790321
4736-60-1	07790296
7782-50-5	12790322 * 12790329 *

APPENDIX C. STATUS REPORTS BY CAS REGISTRY NUMBER (contd.)

CAS NUMBER	SUBMISSION NO.
7789-06-2	10790318
12108-13-3	10790211 FOLLOW UP RESPONSE
14040-11-0	09790311
17786-43-5	07790296
25068-38-6	07790292
25155-23-1	10790317
35835-94-0	07790296
64741-44-2	08790301
64741-59-9	08790301
64741-66-8	10790312
68109-57-9	08790251 SUPPLEMENT
68410-07-1	07790297
68937-40-6	10790317
68937-41-7	10790317

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APPENDIX D. STATUS REPORTS BY STUDY TYPE

STUDY TYPE	SUBMISSION NO.	
ACUTE/SUBCHRONIC TOXICITY - ANIMAL STUDY	07790295	
	07790296	
	09790311	
	10790312	
	12790325	
CARCINOGENICITY - ANIMAL STUDY	07790297	
	09790305	
	09790306	
	10790314	
	11790316	
	11790318	
	01800327	
	01800328S	
	11790028	SUPPLEMENT
	08790250	FOLLOW UP RESPONSE
	08790251	SUPPLEMENT
	10790262	FOLLOW UP RESPONSE
CHEMICAL/PHYSICAL PROPERTIES	07790294	
	11790317	
	07790010	FOLLOW UP RESPONSE
ENVIRONMENTAL EXPOSURE/RELEASE/FATE	07790299	*
	08790300	
	09790310	
	11790319	
	12790322	*
	01800324	
	12790329	*
	01800330	

APPENDIX D. STATUS REPORTS BY STUDY TYPE (contd.)

STUDY TYPE	SUBMISSION NO.
EXPOSURE INFORMATION - POTENTIAL HAZARDOUS USE	07790292
	11790320
	09790326
HUMAN TOXICITY	07790292
	08790304 *
	10790315 *
MUTAGENICITY STUDY	07790293
	07790294
	08790301
	11790321
	12790323
	01800328S
REPRODUCTIVE SYSTEM/TERATOGENICITY - ANIMAL STUDY	07790293
	10790211 FOLLOW UP RESPONSE

* Based on a preliminary evaluation, EPA believes that the information in this submission does not warrant being reported under Section 8(e). In some instances, a submitting company has been requested to provide the basis for its contention that the information reported shows reasonable support for a conclusion of substantial risk.

APPENDIX E. STATUS REPORTS BY SUBMISSION NUMBER

SUBMISSION NO.		CHEMICAL(S)	SUBMITTING COMPANY
07790292		BISPHENOL A-EPICHLOROHYDRIN RESINS EPICHLOROHYDRIN	EMPLOYEE SUBMISSION
07790293		N-ALKYL GLYCIDYL ETHERS (C2-C10)	PROCTER & GAMBLE COMPANY
07790294		MORPHOLINE	TEXACO INC.
07790295		DIRECT BLACK 38	IBM CORPORATION
07790296		BENZYLTRIPHENYLPHOSPHONIUM CHLORIDE ETHYLTRIPHENYLPHOSPHONIUM ACID ACETATE ETHYLTRIPHENYLPHOSPHONIUM IODIDE PHOSPHONIUM ACID COMPOUNDS TETRABUTYLPHOSPHONIUM ACID ACETATE	CINCINNATI MILACRON CHEMICALS INC.
07790297		SRC-II HEAVY DISTILLATE	GULF MINERAL RESOURCES CO.
07790299	*	CARBOFURAN FURADAN 10-G (10% GRANULAR)	FMC CORPORATION
08790300		ACRYLONITRILE	CINCINNATI MILACRON CHEMICALS INC.
08790301		HOME HEATING OIL (NO. 2) PETROLEUM DISTILLATE (LIGHT CATALYTIC CRACKED) PETROLEUM DISTILLATE (STRAIGHT RUN MIDDLE)	UNION OIL COMPANY OF CALIFORNIA
08790304	*	ORGANIC SOLVENTS	EMPLOYEE SUBMISSION
09790305		ETHYLENE OXIDE	UNION CARBIDE CORPORATION

APPENDIX E. STATUS REPORTS BY SUBMISSION NUMBER (contd.)

SUBMISSION NO.		CHEMICAL(S)	SUBMITTING COMPANY
09790306		COAL DERIVED FUEL OIL FRACTIONS (EXPERIMENTAL)	EXXON CORPORATION
09790310		BENZENE, CHLORO- CARBON TETRACHLORIDE CHLOROFORM ETHANE, 1,1-DICHLORO- ETHANE, 1,1,1-TRICHLORO- ETHANE, 1,1,2-TRICHOLRO- ETHANE, 1,2-DICHLORO- ETHENE, 1,2-DICHLORO-, (E) ETHYLENE, TETRACHLORO- ETHYLENE, TRICHLORO- ETHYLENE, 1,1-DICHLORO-	AEROJET-GENERAL CORPORATION
09790311		DIALLYL DIGLYCOL CARBONATE HYDROQUINONE MONOMETHYL ETHER MALEIC ANHYDRIDE TUNGSTEN HEXACARBONYL	PPG INDUSTRIES, INC.
10790312		NAPHTHA (PETROLEUM), LIGHT ALKYLATE ISOPAR C VARSOL 40	EXXON COMPANY, U.S.A.
10790314		FORMALDEHYDE	CIIT
10790315	*	ARGUS Q-328 (MARK-328) POLYGARD THIODIPROPIONATE ESTER COMPLEX TRI (MIXED MONO AND DINONYLPHENYL) PHOSPHITE	STANDARD OIL COMPANY (INDIANA)
10790316		COAL DERIVED FUEL OIL FRACTION (EXPERIMENTAL)	EXXON COMPANY, U.S.A.

APPENDIX E. STATUS REPORTS BY SUBMISSION NUMBER (contd.)

SUBMISSION NO.	CHEMICAL(S)	SUBMITTING COMPANY
10790317	ARYL PHOSPHATES KRONITEX (R) 50 KRONITEX (R) 100 KRONITEX (R) 200 KRONITEX (R) 200B PHENOL, DIMETHYL-, PHOSPHATE (3:1) PHENOL, ISOBUTYLENATED, PHOSPHATE (3:1) PHENOL, ISOPROPYLATED, PHOSPHATE (3:1) PHOSPHORIC ACID, TRIPHENYL ESTER PHOSPHORIC ACID, TRITOLYL ESTER	FMC CORPORATION
10790318	STRONTIUM CHROMATE	CIBA-GEIGY CORPORATION
10790319	POLYCHLORINATED BIPHENYLS	INTERNATIONAL SALT COMPANY
10790320	DIOXANE, 1,4- ETHOXYLATED PRODUCTS	SHEREX CHEMICAL COMPANY INC.
10790321	C. I. DISPERSE BLUE 7 DYE	TOMS RIVER CHEMICAL CORPORATION
12790322 *	CHLORINE	CLOROX COMPANY
12790323	JET FUEL A	ATLANTIC RICHFIELD COMPANY
01800324	CHLOROFORM ETHER, BIS(CHLOROMETHYL) METHANE, DICHLORO-	DIAMOND SHAMROCK CORPORATION
12790325	s-TRIAZINE-2,4,6-TRITHIOL	AMERICAN CYANAMID COMPANY

APPENDIX E. STATUS REPORTS BY SUBMISSION NUMBER (contd.)

SUBMISSION NO.		CHEMICALS	SUBMITTING COMPANY
09790326		ALCOHOL ETHOXYSULFATE (AMMONIUM SALT) ALCOHOL ETHOXYSULFATE (SODIUM SALT) DIOXANE, 1,4-	SHELL OIL COMPANY
01800327		ARCO LB-7979 PROVALENT 4A	ATLANTIC RICHFIELD COMPANY
01800328S		DIMETHYLHYDANTOIN - DERIVED EPOXY RESIN (DEVELOPMENTAL)	CIBA-GEIGY CORPORATION
12790329	*	CHLORINE	E. I. DUPONT DE NEMOURS & COMPANY
01800330		BENZENE, CHLORO- POLYCHLORINATED BIPHENYLS	GENERAL ELECTRIC COMPANY
07790010 FOLLOWUP RESPONSE		ORGANIC SOLVENTS	AMERICAN PETROLEUM INSTITUTE
11790028 SUPPLEMENT		NEOPENTYLGLYCOL DIACRYLATE	UNION CARBIDE CORPORATION
10790211 FOLLOWUP RESPONSE		METHYLCYCLOPENTADIENYL MANGANESE TRICARBONYL	ETHYL CORPORATION
08790250 FOLLOWUP RESPONSE		ACRYLIC ACID, ETHYL ESTER	CELANESE CORPORATION

SUBMISSION NO.	CHEMICAL(S)	SUBMITTING COMPANY
08790251 SUPPLEMENT	ACETOPHENONE, 2',2'-DI(SEC-BUTOXY)	UNION CARBIDE CORPORATION
10790262 FOLLOWUP RESPONSE	ACRYLIC ACID, 2-ETHYLHEXYL ESTER	UNION CARBIDE CORPORATION

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NOTE: The following document control numbers are considered VOID due to clerical errors made during the EPA logging of Section 8(e) documents.

8EHQ-XXXX-0298
8EHQ-XXXX-0302
8EHQ-XXXX-0303
8EHQ-XXXX-0307
8EHQ-XXXX-0308
8EHQ-XXXX-0309
8EHQ-XXXX-0313